# NEVADA STATE
# BOARD OF PHARMACY

## BOARD MEETING

## September 6-7, 2023

## Zoom
## https://zoom.us/j/5886256671
## Meeting ID: 5886256671

Please do not remove the book from the meeting room.

# Nevada State Board of Pharmacy

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E-mail: pharmacy@pharmacy.nv.gov • Website: bop.nv.gov


Date Posted: August 24, 2023

AMENDED AGENDA

◈ PUBLIC NOTICE ◈

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday, September 6, 2023, at 9:00 am. The meeting will continue, Thursday, September 7, 2023, at 9:00 am if necessary or until the Board concludes its business. Pursuant to NRS 241.023(1)(c) the meeting is being conducted by means of remote technology. The public may attend the meeting via live stream remotely or at the following location:

Hilton Garden Inn
7830 S Las Vegas Boulevard
Las Vegas, NV

Via Videoconference at Zoom: https://zoom.us/j/5886256671
or
Via Teleconference at 1 (669) 900-6833
Meeting ID: 588 625 6671

Please Note:

**In regulating the practice of pharmacy, the Nevada State Board of Pharmacy has a duty to carry out and enforce the provisions of Nevada law to protect the health, safety, and welfare of the public.**

Please note that items on this agenda may be taken out of order, two or more agenda items may be combined for consideration, and/or items may be removed from the agenda or delayed for discussion at any time.

The Board may convene in closed session pursuant to NRS 241.030 to consider the character, alleged misconduct, professional competence or physical or mental health of any person named on this agenda.

The Board will take public comment on any matters within their jurisdiction, control, or advisory power. Public comments may be limited to three minutes per person. Public comment may also be submitted to the Board at teambc@pharmacy.nv.gov .

The Board may refuse to consider public comment related to a contested case pursuant to NRS 233B.126 until the Board has rendered a decision in the contested case.

1. Call to Order and Roll Call – Establishment of Quorum

2. Public Comment: No action may be taken upon a matter raised under this item of the agenda until the matter itself has been specifically included on a future agenda as an item. (NRS 241.020)

◈ CONSENT AGENDA ◈

The Consent Agenda contains matters of routine acceptance. The Board Members may approve the consent agenda items as written or, at their discretion, may address individual items for discussion or change.

3. Approval of the July 12-13, 2023, Board Meeting Minutes (**FOR POSSIBLE ACTION)**

4. 4.1 Applications for Out-of-State Medical, Devices, Equipment and Gases License (NAC 639.6944) – Non-appearance **(FOR POSSIBLE ACTION)**

A. Healthcare HD LLC – Dunedin, FL

4.2 Applications for Out-of-State Wholesaler License (NRS 639.233) – Non-appearance (**FOR POSSIBLE ACTION**)

**Background Check Not Required by Law.**

4.2.1 Distributor for Single Manufacturer (NAC 639.593(7)(e))

B. QuVa Pharma, Inc. – Phoenix, AZ

4.2.2 Manufacturer (NAC 639.593(7)(d))

C. Albiero Pharma, Inc. – Boston, MA
D. Ascend Laboratories LLC – Parsippany, NJ
E. Brainlab Inc. – Westchester, IL
F. Cerapedics Inc. – Westminster, CO
G. Coloplast Corp. – Lithia Springs, GA
H. Coloplast Corp. – Minneapolis, MN
I. Coloplast Corp. – North Mankato, MN
J. Corium, LLC – Boston, MA
K. Cranbury Pharmaceuticals, LLC – Monmouth Junction, NJ
L. Fidia Pharma USA Inc. – Florham Park, NJ
M. Medline Industries, LP – Mundelein, IL
N. Neotech Products LLC – Valencia, CA
O. OxyGo HQ Florida LLC – Orlando, FL
P. Philips Healthcare, a division of Philips North America LLC – Bothell, WA
Q. Philips Healthcare, a division of Philips North America LLC – Cambridge, MA
R. Philips Image Guided Therapy Corporation – Rancho Cordova, CA

S. Philips Ultrasound LLC – Bothell, WA
T. Phoenix Assurance, LLC – Memphis, TN
U. Respironics Logistics Services, LLC – Mt. Pleasant, PA
V. UPS Supply Chain Solutions, Inc. – Mira Loma, CA
W. Verity Pharmaceuticals Inc. – Ewing, NJ

4.2.3 Publicly Traded (NAC 639.593(7)(a))

4.2.4 VAWD-Accredited (NAC 639.593(7)(c))

X. AmerisourceBergen Drug Corporation – Denver, CO
Y. Gemco Medical – Hudson, OH
Z. Maks Pharma and Diagnostics Inc. – Baldwin, NY

4.2.5 Manufacturer and VAWD-Accredited (NAC 639.593(7)(c) and (d))

AA. Apotex Corp. – Plainfield, IN
BB. AstraZeneca Pharmaceuticals LP – Shepherdsville, KY

4.2.6 Publicly Traded and Manufacturer (NAC 639.593(7)(a) and (d))

CC. Aadi Bioscience, Inc. – Pacific Palisades, CA
DD. Boston Scientific Corporation – Brooklyn Park, MN
EE. Chemocentryx Inc. – San Carlos, CA

4.2.7 Publicly Traded and VAWD-Accredited (NAC 639.593(7)(a) and (c))

**4.2.8 Background checks completed in compliance with NRS 639.500.**

FF. Fountain Medical Supplies Inc. – Orem, UT
GG. MD Logistics LLC – Garner, NC
HH. Skyline Pharmaceuticals, Inc. – Ft. Lauderdale, FL

4.3 Applications for Nevada Wholesaler License (NRS 639.233) – Non-appearance (**FOR POSSIBLE ACTION**)

4.3.1 Manufacturer (NAC 639.593(7)(d))

4.3.2 **Background checks completed in compliance with NRS 639.500.**

4.4 Application for Nevada Pharmacy License (NRS 639.230) – Non-appearance **(FOR POSSIBLE ACTION)**

II. Dignity Specialty Pharmacy – Las Vegas, NV
JJ. ER at Damonte Ranch, an Extension of Northern Nevada Sierra Medical Center – Reno, NV

4.5 Application for Nevada Compounding Pharmacy License (NRS 639.230) – Non-appearance **(FOR POSSIBLE ACTION)**

KK. Sky Vista Pharmacy – Las Vegas, NV

4.6 Applications for Nevada Medical, Devices, Equipment and Gases License (NAC 639.6944) – Non-appearance **(FOR POSSIBLE ACTION)**

4.7 Application for Out-of-State Compounding Pharmacy License (NRS 639.230) – Non-Appearance – **(FOR POSSIBLE ACTION)**

LL. Brava CA LLC – Novato, CA
MM. Kings Park Slope, LLC – Brooklyn, NY

4.8 Application for Out-of-State Pharmacy License (NRS 639.2328) – Non-appearance **(FOR POSSIBLE ACTION)**

NN. Ascension Rx 1001 – Austin, TX
OO. Brightside Specialty Pharmacy – Santa Ana, CA
PP. Burt's Pharmacy Moorpark – Moorpark, CA
QQ. PRxP of CA, LLC – Ontario, CA
RR. SKNV Pharmacy, LLC – Deerfield Beach, FL
SS. URGENTMEDRX, LLC – Boca Raton, FL

4.9 Application for Ambulatory Surgery Center License (NAC 639.4992) – Non- Appearance **(FOR POSSIBLE ACTION)**

TT.Surgery Center of Reno, LLC – Reno, NV

4.10 Request to Engage in the Practice of Pharmacy at a Site Other than a Licensed Pharmacy – Non-appearance **(FOR POSSIBLE ACTION)**

UU. Trenie Kunke
VV. Zachary Rosko

4.11 Recommended Denial of Registration/Licensure Due to Material Omissions in Application – Non-Appearance **(FOR POSSIBLE ACTION)**

WW. Alonda Holt
XX. Jennifer Jaycox
YY. Vesta Johnson
ZZ.Rebeka Ojakhyan

◈ REGULAR AGENDA ◈

5. Disciplinary hearings pursuant to NRS 639.247. (**FOR POSSIBLE ACTION**)

A. Maria Cruz RPh (18-021-RPH-D-S)
B. Roosevelt Watson, MD (22-112-CS-S)
C. Walgreens Pharmacy #6425 (22-359-PH-S)
D. Juan Peidra Flores, RPh (22-359-RPH-S)
E. CVS Pharmacy #8804 (19-131-PH-S)
F. Sandra Le, RPh (19-131-RPH-A-S)
G. Khanh V. Pham, RPh (19-131-RPH-B-S)
H. Genoa Healthcare LLC (20-022-PH-S)
I. Craig Pivo, RPh (20-022-RPH-S)
J. Smith's Pharmacy #390 (22-429-PH-N)
K. Delta Drugs (20-168-PH-S)
L. Ryan Ross, PT (20-027-PT-S)
M. Preferred Homecare (22-415-MP-N)
N. Carson Tahoe Regional Medical Center (23-004-PH-N)
O. Kelly Schott, RPh (23-004-RPH-N)
P. Edward Victoria, MD (23-113-CS-S)

6. Appeal hearing pursuant to NRS 639.2895(2) (**FOR POSSIBLE ACTION**)

A. Cobalt Medical Supply Inc. (23-122-O)

7. Stipulated Rehearing **(FOR POSSIBLE ACTION)**

A. Las Vegas Scripts Rx (19-243-PH-S)
B. Nathan Edouard, RPH (19-243-RPH-S)

8. Application for Out-of-State Compounding Pharmacy License (NRS 639.230) – Appearance – **(FOR POSSIBLE ACTION)**

A. Brava NC LLC – Morrisville, NC
B. Primera Professional Pharmacy – Sugar Land, TX
C. Town Total Compounding Center – Woodbury, NY
D. WP Pharma Labs, Inc. – Dallas, TX
E. 1st Choice Pharmacy – Holiday, FL

9. Application for Out-of-State Pharmacy License (NRS 639.230) – Appearance – **(FOR POSSIBLE ACTION)**

Seven Hills Pharmacy, LLC – Sharonville, OH

10. Application for Out-of-State Outsourcing Facility (NRS 639.100) – Appearance (**FOR POSSIBLE ACTION**)

A. BPI Labs, LLC – Largo, FL
B. Hikma Injectables USA Inc. – Dayton, NJ
C. PQ Pharmacy – Brooksville, FL
D. STERRX, LLC – Plattsburgh, NY

11. Applications for Out-of-State Wholesalers License (NRS 639.233) Appearance **(FOR POSSIBLE ACTION)**

    STERRX, LLC – Plattsburgh, NY – Background Check Not Required - VAWD-Accredited (NAC 639.593(7)(c))

12. Applications for Nevada Wholesalers License (NRS 639.233) Appearance **(FOR POSSIBLE ACTION)**

    Reliable Healthcare Logistics, LLC – Reno, NV

13. Applications for Pharmaceutical Technician in Training Registration (NAC 639.242) – Appearance. (**FOR POSSIBLE ACTION)**

    A. Adrianna Rivera
    B. Bernice Benscoter

14. Application for Pharmacist Registration by Reciprocation NRS 639.134) – Appearance (**FOR POSSIBLE ACTION**)

    James Arnett

15. Petition for Reinstatement of Controlled Substance Registration – Appearance. **(FOR POSSIBLE ACTION)**

    Ronald Smith

16. Application for Physician Assistant -Prescribe/Controlled Substance Registration – Appearance **(FOR POSSIBLE ACTION)**

    Aaron Kuehl

17. Discussion and possible action to request an Attorney General Opinion pursuant to NRS 228.150 on the authority of a Nevada-licensed homeopathic physician to prescribe or dispense a controlled substance or dangerous drug. **(FOR POSSIBLE ACTION)**

◈ WORKSHOP ◈

Thursday September 7, 2023 – 9:00 am

18. Notice of Proposed Regulation Workshop Pursuant to NRS 233B.061(2) **(FOR POSSIBLE ACTION):**

A. **Amendment of Nevada Administrative Code (NAC) 639.694: Administrator required.** The proposed amendment to NAC 639.694 will allow for an inventory of certain durable medical equipment to be stored at a licensed hospital and provided to patients upon discharge from the hospital.

B. **Amendment of Nevada Administrative Code (NAC) 639.520: Security of Prescription Departments Administrator required.** Current law imposes certain requirements for the security of a pharmacy. The Board will solicit comments regarding these requirements.

C. **Amendment of Nevada Administrative Code (NAC) 639.XXX: Administrative Fine in Lieu of Disciplinary Action.** The proposed amendment clarifies the circumstances when the Board may assess an administrative fine pursuant to NRS 639.2895 in lieu of taking formal disciplinary action against a holder of a certificate, certification, license, or permit issued by the Board. With respect to minor violations, the proposed amendment further limits the amount of the fine that could otherwise be imposed pursuant to NRS 639.2895.

D. **Amendment of Nevada Administrative Code (NAC) 639.XXX: Assembly Bill No. 156 (2023) – An Act Relating to Substance Use Disorders.** This law requires the Board to adopt regulations related to: (a) The requirements to register with the Board to engage in the activity authorized by this section; and (b) Establishing a protocol for the actions authorized by the bill.

◈ PUBLIC HEARING ◈

Thursday September 7, 2023 – 9:00 am

19. Notice of Proposed Regulation Public Hearing Pursuant to NRS 233B.061(2) **(FOR POSSIBLE ACTION):**

A. **Amendment to the Nevada Administrative Code ("NAC") 639.** The proposed amendments relate to the licensing requirements for facilities for treatment with narcotics and provide other matters properly relating thereto. (LCB File No. R196-22)

20. General Counsel Report. Note: The Board may exclude the public for a report on potential or existing litigation pursuant to NRS 241.015(3)(b)(2).

21. Executive Secretary Report:

A. Financial Report
B. Issuance of Temporary Licenses and Registrations
C. Change of Address Business List
D. Meetings with Other Health Care Regulatory Boards

E. COVID-19 Response
F. Licensing Software Update
G. Licensing Activities Report
H. PMP Integration
I. Citations & Fines issued pursuant to NRS 632.2895

22. Date and Location of Next Scheduled Board Meeting:

October 11-12, 2023 – Las Vegas, NV

23. Public Comment: No action may be taken upon a matter raised under this item of the agenda until the matter itself has been specifically included on a future agenda as an item. (NRS 241.020)

24. Adjournment

Note: We are pleased to make reasonable accommodations for members of the public who are disabled and wish to attend the meeting. If special arrangements for the meeting are necessary, please notify the Nevada State Board of Pharmacy, 985 Damonte Ranch Parkway, Suite 206, Reno, NV, 89521, or call Kristopher Mangosing at (775) 850-1440, as soon as possible.

Supporting materials or additional information regarding the meeting may be obtained from Shirley Hunting at (775) 850-1440, email shunting@pharmacy.nv.gov or 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada, 89521.

Continuing Education credit will be given for in-person attendance at this Board meeting pursuant to NAC 639.330(1)(b)(2).

This notice has been posted at www.notice.nv.gov and www.bop.nv.gov pursuant to NRS 241.020 (4).

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# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206, Reno, NV 89521

(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444

• Web Page: bop.nv.gov

MINUTES

July 12-13, 2023

BOARD MEETING

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday, July 12, 2023, at 9:00 am. The meeting will continue, Thursday, July 13, 2023, at 9:00 am if necessary or until the Board concludes its business. Pursuant to NRS 241.023(1)(c) the meeting is being conducted by means of remote technology. The public may attend the meeting via live stream remotely or at the following location:

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

Via Videoconference at Zoom: https://zoom.us/j/5886256671
or
Via Teleconference at 1 (669) 900-6833
Meeting ID: 588 625 6671

Board Members Present:

| | | | |
|---|---|---|---|
| Helen Park | Krystal Freitas | Jade Jacobo | Wayne Mitchell |
| Rolf Zakariassen | Richard Tomasso | Gener Tejero | |

Board Staff Present:

| | | | |
|---|---|---|---|
| Dave Wuest | Yenh Long | Shirley Hunting | Kristopher Mangosing |
| Brett Kandt | Peter Keegan | Gregory Zunino | Darlene Nases |
| Joe Dodge | Mui Lee | Sophia Long | |

President Park read the mission statement of the Nevada State Board of Pharmacy to reiterate the Board's duty to carry out and enforce the provisions of Nevada Law to protect the health, safety, and welfare of the public.

Dave Wuest stated that this Board Meeting is being held over Zoom and is in compliance with the Governor's directive and Open Meeting Laws for Nevada.

1. Call to Order and Roll Call – Establishment of Quorum

President Park performed the roll call. All Board members were present, and a quorum was established.

2. Public Comment July 12, 2023, 9:00 AM

There was no public comment.

◈ CONSENT AGENDA ◈

The Consent Agenda contains matters of routine acceptance. The Board Members may approve the consent agenda items as written or, at their discretion, may address individual items for discussion or change.

3. Approval of the June 14-15, 2023, Board Meeting Minutes (**FOR POSSIBLE ACTION)**

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve June 14-15, 2023, Board Meeting minutes.

Second: Wayne Mitchell

Action: Passed unanimously.

4. 4.1 Applications for Out-of-State Medical, Devices, Equipment and Gases License (NAC 639.6944) – Non-appearance **(FOR POSSIBLE ACTION)**

A. Avanos Medical Sales, LLC – Alpharetta, GA
B. CCS Medical – Clearwater, FL
C. Embody, Inc. – Norfolk, VA
D. Orthofix US LLC – Lewisville, TX
E. RS Medical – Vancouver, WA
F. Veterans Choice Medical Equipment, LLC – West Valley City, UT

4.2 Applications for Out-of-State Wholesaler License (NRS 639.233) – Non-appearance (**FOR POSSIBLE ACTION**)

**Background Check Not Required by Law.**

4.2.1 Distributor for Single Manufacturer (NAC 639.593(7)(e))

4.2.2 Manufacturer (NAC 639.593(7)(d))

G. ALOM Technologies Corporation – Fremont, CA
H. Analog Pharma – Princeton, NJ
I. Ascend Therapeutics US, LLC – Herndon, VA
J. Ascend Therapeutics US, LLC – Morristown, NJ
K. BE Pharmaceuticals, Inc. – Cary, NC
L. Biocon Biologics Inc. – Cambridge, MA
M. Celltrion USA, Inc. – Jersey City, NJ
N. Cytrellis Biosystems, Inc. – Woburn, MA
O. Lynch Biologics, LLC – Franklin, TN
P. Marius Pharmaceuticals LLC – Raleigh, NC
Q. Matheson Tri-Gas, Inc. – Mesa, AZ
R. Matheson Tri-Gas, Inc. – Richmond, CA
S. Matheson Tri-Gas, Inc. – Tualatin, OR
T. Matheson Tri-Gas, Inc. – Vacaville, CA
U. Medline Industries, LP – Glen Falls, NY
V. Micro-Tech Endoscopy USA, Inc. – Ann Arbor, MI
W. Monteris Medical Corporation – Minnetonka, MN
X. Myonex LLC – Horsham, PA
Y. Neotech Products LLC – Valencia, CA
Z. Nobelpharma America, LLC – Bethesda, MD
AA. Oyster Point Pharma, Inc. – Princeton, NJ
BB. Philips RS North America LLC – Mt. Pleasant, PA
CC. Phoenix Assurance, LLC – Fort Worth, TX
DD. Phoenix Assurance, LLC – Moreno Valley, CA
EE. Quipment, Inc. – Kennesaw, GA
FF. Reliable HealthCare Logistics, LLC – Boca Raton, FL
GG. Reliable HealthCare Logistics, LLC – Dayton, NJ
HH. Reliable HealthCare Logistics, LLC – Lockbourne, OH
II. Reliable HealthCare Logistics, LLC – Pompano Beach, FL
JJ. Reliable HealthCare Logistics, LLC – Sugarland, TX
KK. RS Medical – Vancouver, WA
LL. Trigen Laboratories, LLC – Alpharetta, GA

4.2.3 Publicly Traded (NAC 639.593(7)(a))

MM. Agiliti Health, Inc. – McDonough, GA
NN. Agiliti Health, Inc. – Memphis, TN
OO. Agiliti Health, Inc. – Phoenix, AZ
PP. Agiliti Health, Inc. – Salt Lake City, UT
QQ. Antares Pharma, Inc. – Ewing, NJ
RR. Krystal Biotech, Inc. – Pittsburgh, PA
SS. Orthofix Services LLC – Lewisville, TX
TT. Optum Specialty Distribution, LLC – Etna, OH
UU. Smith & Nephew, Inc. – Memphis, TN
VV. Syndax Pharmaceuticals, Inc. – Waltham, MA
WW. VIEMED – Lafayette, LA

4.2.4 VAWD-Accredited (NAC 639.593(7)(c))

XX. American Pharmaceutical Ingredients LLC – Waterford Township, MI

4.2.5 Manufacturer and VAWD-Accredited (NAC 639.593(7)(c) and (d))

4.2.6 Publicly Traded and Manufacturer (NAC 639.593(7)(a) and (d))

YY. Acclarent, Inc. – Irvine, CA
ZZ. Artivion, Inc. – Kennesaw, GA
AAA. BFLY Operations, Inc. – Burlington, MA
BBB. Genmab US, Inc. – Plainsboro, NJ
CCC. Orthofix US LLC – Lewisville, TX
DDD. Shockwave Medical, Inc. – Santa Clara, CA

4.2.7 Publicly Traded and VAWD-Accredited (NAC 639.593(7)(a) and (c))

EEE. Henry Schein, Inc. – Indianapolis, IN

**4.2.8 <u>Background checks completed in compliance with NRS 639.500.</u>**

FFF. AleraCare Wholesale, LLC – Phoenix, AZ
GGG. Clinical Resources Incorporated – Towson, MD
HHH. Medline Industries, LP – Katy, TX
III. Medline Industries, LP – Mebane, NC
JJJ. Medline Industries, LP – Salt Lake City, UT
KKK. Medline Industries, LP – Saint Peters, MO
LLL. Medline Industries, LP – Temecula, CA
MMM. Mountainside Medical Equipment, Inc. – Marcy, NY
NNN. NDC Distributors – Cranbury, NJ
OOO. NDC Homecare LLC – Camp Hill, PA
PPP. NDC Homecare LLC – Conway, AR
QQQ. Prime Pharma Solutions – Dallas, TX
RRR. SMS Ambassadors Corp – Toledo, OH

4.3 Applications for Nevada Wholesaler License (NRS 639.233) – Non-appearance (**FOR POSSIBLE ACTION**)

4.3.1 Manufacturer (NAC 639.593(7)(d))

SSS. Matheson Tri-Gas, Inc. – Sparks, NV
TTT. Preferred Homecare – Las Vegas, NV

4.3.2 **<u>Background checks completed in compliance with NRS 639.500.</u>**

4.4 Application for Nevada Pharmacy License (NRS 639.230) – Non-appearance **(FOR POSSIBLE ACTION)**

UUU. Sierra Specialty Pharmacy – Reno, NV

4.5 Application for Nevada Compounding Pharmacy License (NRS 639.230) – Non-appearance **(FOR POSSIBLE ACTION)**

VVV. Sierra Compounding Pharmacy – Reno, NV

4.6 Applications for Nevada Medical, Devices, Equipment and Gases License (NAC 639.6944) – Non-appearance **(FOR POSSIBLE ACTION)**

WWW. Care Chest – Las Vegas, NV
XXX. FutureCare – Las Vegas, NV

4.7 Application for Out-of-State Compounding Pharmacy License (NRS 639.230) – Non-Appearance – **(FOR POSSIBLE ACTION)**

4.8 Application for Out-of-State Pharmacy License (NRS 639.2328) – Non-appearance **(FOR POSSIBLE ACTION)**

YYY. BioPlus Specialty Pharmacy Services, LLC – Irvine, CA
ZZZ. CenterWell Pharmacy, Inc. – Irving, TX
AAAA. Gifthealth Pharmacy – Columbus, OH
BBBB. Hometown Pharmacy – Crestview, FL
CCCC. Kindred Care Pharmacy – Calabasas, CA
DDDD. Kroger Health Connect UC – Cincinnati, OH
EEEE. MOBE, LLC – Minneapolis, MN
FFFF. Regional One Health Pharmacy Stage Post – Bartlett, TN
GGGG. Walmart Central Fill #2670 – Spring, TX

4.9 Application for Ambulatory Surgery Center License (NAC 639.4992) – Non- Appearance **(FOR POSSIBLE ACTION)**

4.10 Application for Nevada Warehouse (NAC 639. ) – Non- Appearance **(FOR POSSIBLE ACTION)**

HHHH. Accelerated Care Plus, Corp – Reno, NV
IIII. JW Welding Supplies & Tools – Sparks, NV

Rolf Zakariassen recused himself from Agenda Item 4WWW due to Care Chest receiving financial and product contributions from his employer.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve Consent Agenda excluding Agenda Item 4WWW.

Second: Krystal Freitas

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to approve Consent Agenda Item 4WWW.

Second: Krystal Freitas

Action: Passed unanimously (Zakariassen recused).

◈ REGULAR AGENDA ◈

5. Disciplinary hearings pursuant to NRS 639.247. (**FOR POSSIBLE ACTION**)

C. Smith's Pharmacy #389 (22-344-PH-N)

Andrea Adams, Pharmacy Practice Coordinator, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Peter Keegan, General Counsel for the Nevada Board of Pharmacy, prosecuted the case regarding the pharmacy failing to notify the Board of a change in managing pharmacist and a lapse of an employed managing pharmacist for the pharmacy.

Mr. Keegan notified the Board members that an Answer and Notice of Defense was submitted to the Board.

Mr. Keegan presented a proposed Stipulation and Order for the Board's consideration.

The proposed stipulated penalties for Smith's Pharmacy #389 Pharmacy License No. PH00976 for Case No. 22-344-PH-N are the following: 1) pay a fine of $5,000; and 2) pay $500 to partially reimburse the Board for recoverable attorney's fees and investigative costs.

The Board questioned the changes the pharmacy made to ensure that this will not happen again.

Ms. Adams answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Stipulation and Order as presented by Mr. Keegan.

Second: Rolf Zakariassen

Action: Passed unanimously.

D. Preferred Homecare (22-415-MP-N)

This matter was continued to a future Board Meeting.

E. Jason Dean Bigelow (22-501-RPH-N)

Jason Bigelow appeared and was sworn in by President Park prior to answering questions and offering testimony.

Chris Rusby appeared as counsel on behalf of Mr. Bigelow.

Peter Keegan prosecuted the case alleging Mr. Bigelow diverted six 10mg of Oxycodone tablets from Costco Pharmacy #127.

Mr. Keegan and Mr. Rusby have stipulated to Exhibits to be entered into the record.

Mr. Keegan requested that Exhibits 1, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, and 18 be entered into the record.

Mr. Rusby requested that Respondent Exhibits 2, 3, 4, 5, 6, 7, and 8 be entered into the record.

President Park admitted Mr. Keegan's Exhibits and Mr. Rusby's Respondent's Exhibits.

Mr. Keegan commented that Mr. Rusby admitted Exhibit 8 which talks about Mr. Bigelow's character in witness statements.

Mr. Rusby commented that admittance of Respondent's Exhibit 8 was an error and requested to withdraw.

President Park denied motion to withdraw Respondent's Exhibit 8.

Mr. Rusby requested that Danielle Dulisse and Kate Bryte be excluded from hearing.

Mr. Keegan commented that we exclude all witnesses from hearing.

Mr. Keegan called Danielle Dulisse, Costco Pharmacy #127 - Managing Pharmacist, as a witness.

Danielle Dulisse appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Keegan questioned Ms. Dulisse on her position and the case regarding Mr. Bigelow.

Mr. Rusby cross-examined Ms. Dulisse.

The Board questioned Ms. Dulisse.

Mr. Keegan called Kate Bryte, District Manager for Loss Prevention at Save Mart, as a witness.

Kate Bryte appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Keegan questioned Ms. Bryte on her position and the investigation regarding Mr. Bigelow.

Mr. Keegan questioned Ms. Bryte on proposed Exhibit 16 which was the employment action form for Mr. Bigelow.

Mr. Keegan requested that Exhibit 16 be entered into the record.

Mr. Rusby objected to Exhibit 16.

President Park overruled and admitted Exhibit 16.

Mr. Keegan questioned the proposed Exhibit 17 which was Save Mart's Investigation Report of the controlled substance drugs that were lost.

Mr. Keegan requested that Exhibit 17 be entered into the record.

Mr. Rusby objected to Exhibit 17.

President Park overruled and admitted Exhibit 17.

Mr. Rusby cross-examined Ms. Bryte.

The Board questioned Ms. Bryte.

Mr. Rusby called David Straw, Corporate Vice President of Intercept Lab Services, as a witness.

David Straw appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Rusby questioned Mr. Straw on his position and the drug test that he took of Mr. Bigelow.

Mr. Keegan cross-examined Mr. Straw.

Mr. Rusby called Jason Bigelow as a witness.

President Park commented that Mr. Bigelow is still sworn in.

Mr. Rusby questioned Mr. Bigelow on his experience as a pharmacist and the events that occurred when the six 10mg of Oxycodone tablets went missing.

Mr. Rusby played Respondent's Exhibit for Costco Pharmacy #127 security video of when Mr. Bigelow alleged that the six 10mg of Oxycodone tablets fell into his smock pocket.

Mr. Keegan cross-examined Mr. Bigelow.

Mr. Rusby re-crossed Mr. Bigelow.

The Board questioned Mr. Bigelow.

Mr. Rusby called William Ruebusch, Costco Pharmacy #127 – Relief Pharmacist, as a witness.

Mr. Ruebusch appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Rusby questioned Mr. Ruebusch on working with Mr. Bigelow and his thoughts on the allegations while playing Respondent's Exhibit for Costco Pharmacy #127 security video of Mr. Bigelow.

Mr. Keegan cross-examined Mr. Ruebusch.

The Board questioned Mr. Ruebusch.

Mr. Rusby called Marcos Rodriquez, Costco Pharmacy #127 – Pharmaceutical Technician, as a witness.

Mr. Rodriguez appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Rusby and Mr. Keegan have stipulated to stop playing Respondent's Exhibit for Costco Pharmacy #127 security video of Mr. Bigelow due to security concerns as employees are not aware of the camera angles or blind spots at Costco.

Mr. Rusby questioned Mr. Rodriquez on his position, his thoughts on the allegations against Mr. Bigelow, and his testimony to Costco and to the Nevada Board of Pharmacy.

Mr. Keegan cross-examined Mr. Rodriguez.

The Board questioned Mr. Rodriquez.

Mr. Rusby called Jacob Allen Fleenor, Costco Pharmacy #127 – Pharmaceutical Technician, as a witness.

Mr. Fleenor appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Rusby questioned Mr. Fleenor on his position and the events that occurred on the day of the incident.

Mr. Keegan objected to the testimony as it is becoming very duplicative.

President Park agreed and requested that Mr. Rusby ask different questions.

Mr. Rusby questioned Mr. Fleenor on the allegations against Mr. Bigelow and if anyone contacted him to provide testimony.

President Park expressed concern on Mr. Rusby's next witness and if the line of questioning is duplicative.

Mr. Rusby called Theodore Stuart, Costco Pharmacy #127 – Pharmaceutical Technician, as a witness.

Mr. Stuart appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mr. Rusby questioned Mr. Stuart on his position, the events that occurred on the day of the incident, and if anyone contacted him to provide testimony.

The Board questioned Mr. Stuart.

President Park concluded the case and commented that it will be continued until tomorrow.

Sophia Long, Senior Deputy Attorney General from the Attorney General's Office, clarified that everyone associated with the case should not discuss anything since the hearing is on-going.

6. Appeal hearing pursuant to NRS 639.2895(2) (**FOR POSSIBLE ACTION**)

A. Big R of Sparks (22-139-N)

John McCallister, Secretary Treasurer, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Peter Keegan provided background on the appearance regarding Big R receiving a cease and desist/citation due to unlicensed practice which they are appealing the $5,000 fine.

Mr. McCallister clarified that it was an oversight on their part and will pay a fine, but they believe the fine is excessive.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to uphold the $5,000 fine for Big R of Sparks.

Second: Wayne Mitchell

Action: Passed unanimously.

B. Cobalt Medical Supply Inc. (23-122-O)

This matter was continued to a future Board Meeting.

7. Stipulated Rehearing **(FOR POSSIBLE ACTION)**

A. Las Vegas Scripts Rx (19-243-PH-S)

This matter was continued to a future Board Meeting.

B. Nathan Edouard, RPH (19-243-RPH-S)

This matter was continued to a future Board Meeting.

Public Comment July 12, 2023, 5:11 PM

There was no public comment.

President Park recessed the meeting for the night and reconvened the meeting the next morning.

Board Members Present:

| | | | |
|---|---|---|---|
| Helen Park | Krystal Freitas | Gener Tejero | Wayne Mitchell |
| Rolf Zakariassen | Richard Tomasso | Jade Jacobo | |

Board Staff Present:

| | | | |
|---|---|---|---|
| Dave Wuest | Yenh Long | Shirley Hunting | Kristopher Mangosing |
| Brett Kandt | Peter Keegan | Gregory Zunino | Darlene Nases |
| Joe Dodge | Mui Lee | Sophia Long | |

President Park read the mission statement of the Nevada State Board of Pharmacy to reiterate the Board's duty to carry out and enforce the provisions of Nevada Law to protect the health, safety, and welfare of the public.

Dave Wuest stated that this Board Meeting is being held over Zoom and follows the Governor's directive and Open Meeting Laws for Nevada.

Call to Order and Roll Call – Establishment of Quorum

President Park performed the roll call. All Board members were present, and a quorum was established.

Public Comment July 13, 2023, 9:00 AM

There was no public comment.

◈ PUBLIC HEARING ◈

Thursday July 13, 2023 – 9:00 am

20. Notice of Proposed Regulation Public Hearing Pursuant to NRS 233B.061(2) **(FOR POSSIBLE ACTION):**

**Amendment of Nevada Administrative Code (NAC) 639.** The proposed amendments will add the American Red Cross as a provider of certification in lifesaving techniques. LCB File R198-22

Dave Wuest presented background on the public hearing item regarding Amendment of Nevada Administrative Code (NAC) 639.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Amendment of Nevada Administrative Code (NAC) 639. LCB File R198-22

Second: Krystal Freitas

Action: Passed unanimously.

◈ REGULAR AGENDA ◈

16. Application for Nevada Veterinary Drug Supplier License – (Appearance) **(FOR POSSIBLE ACTION)**

Big R Sparks – Sparks, NV

John McCallister appeared and was sworn in by President Park prior to answering questions and offering testimony.

Dave Wuest provided background on the application.

Board discussion ensued.

Board Action:

Motion: President Park moved to approve the Nevada Veterinary Drug Supplier License for Big R of Sparks.

Second: Wayne Mitchell

Action: Passed unanimously.

5. Disciplinary hearings pursuant to NRS 639.247. (**FOR POSSIBLE ACTION**)

E. Jason Dean Bigelow (22-501-RPH-N)

This is the continued hearing for Jason Bigelow.

Jason Bigelow appeared and was sworn in by President Park prior to answering questions and offering testimony.

Chris Rusby appeared as counsel on behalf of Mr. Bigelow.

Peter Keegan prosecuted the case alleging Mr. Bigelow allegedly diverted six 10mg of Oxycodone tablets from Costco Pharmacy #127.

Board discussion ensued on the factual allegations and if they believe Mr. Bigelow intentionally diverted six 10mg of Oxycodone tablets.

Board Action:

Motion: President Park moved to find that the Board has jurisdiction over this matter. She moved to make Findings of Fact consistent with paragraphs 1-5, paragraph 6 with modification to state, “Respondent Bigelow notified Rodriguez that the vial only confirmed fourteen (14) tablets.”, paragraphs 7, and paragraphs 9-13 of the Notice of Intended Action and Accusation.

Second: Jade Jacobo

Action: Passed unanimously.

Board Action:

Motion: President Park moved to find Jason Bigelow guilty of all Counts One through Counts Four.

Second: Richard Tomasso

Board discussion ensued.

Aye: Park, Tomasso, Zakariassen
Nay: Tejero, Jacobo, Freitas, Mitchell

Action: Motion fails.

Board Action:

Motion: Jade Jacobo moved to find Jason Bigelow not guilty of all Counts One through Counts Four against Jason Bigelow.

Second: Gener Tejero

Aye: Jacobo, Freitas, Tejero
Nay: Park, Tomasso, Zakariassen, Mitchell

Action: Motion fails.

Wayne Mitchell clarified that his vote was because he wanted the Board to discuss each count at Gener Tejero's request.

Board Action:

Motion: President Park moved to find Jason Bigelow guilty of all Counts One through Counts Four.

Second: Richard Tomasso

Aye: Park, Tomasso, Zakariassen, Mitchell
Nay: Tejero, Jacobo, Freitas

Action: Motion carries.

The Board discussed the proposed discipline for Mr. Bigelow.

Board Action:

Motion: President Park moved to make the following penalties for Jason Bigelow's Certificate of Registration No. 18118: 1) is revoked, revocation is stayed and

Bigelow is placed on probation for two years; 2) Respondent Bigelow shall pay a fine of $5,000; and 3) Respondent Bigelow cannot be a Managing Pharmacist at any Nevada license pharmacy.

Second: Richard Tomasso

Aye: Park, Tomasso, Zakariassen, Mitchell
Nay: Tejero, Jacobo, Freitas

Action: Motion carries.

Mr. Keegan requested the Board find attorney's fees and costs were reasonable, necessary, and actually incurred.

Mr. Rusby objected to Monica Segedy's, Nevada Board of Pharmacy Investigator's, timesheet.

President Park overruled and found attorney's fees and costs were reasonable, necessary, and actually incurred.

Board Action:

Motion: President Park moved to award the attorney's fees and costs of $6,690.63 on the basis that they were reasonable, necessary, and actually incurred.

Second: Richard Tomasso

Action: Passed unanimously.

Jade Jacobo was excused from the Board Meeting at 11:25 AM.

A. CVS Pharmacy #4691 (22-104-PH-N)
B. Joseph DeLallo (22-104-RPH-N)

Rolf Zakariassen recused himself due to his employment with CVS.

Joseph DeLallo appeared and was sworn in by President Park prior to answering questions and offering testimony.

William Stilling appeared as counsel on behalf of CVS Pharmacy #4691 and Joseph DeLallo.

Gener Tejero disclosed that he has a business relationship with Mr. Stilling but can participate in this matter fairly and without bias.

Peter Keegan prosecuted the case regarding a misfill of 250 mg Mefloquine, a Malaria prevention drug, that the patient went to the emergency room on suspicion of taking an unknown medication. However, she was discharged in "good" condition.

Mr. Keegan presented Stipulated Facts to the Board.

Mr. Keegan mentioned that Mr. DeLallo had prior discipline with the Board regarding a citation and fine in Case# 19-008-RPH-N for a misfill and another discipline which Mr. DeLallo agreed to a Stipulation and Order in Case# 14-023-RPH-N.

Mr. Stilling called Joseph DeLallo as a witness.

Mr. Stilling questioned Mr. DeLallo on his position and the events that occurred.

The Board questioned Mr. DeLallo.

Mr. Keegan proposed a fine against Mr. DeLallo and CVS Pharmacy #4691 for the violations.

Mr. Stilling requested that the disciplines against Mr. DeLallo not be taken into account as the citation and fine was handled in 2022 when this case is from 2019, and the 2014 discipline was so long ago that it is not relevant. In addition, he is requested that Count Two be dropped. It was Mr. DeLallo's own mistake so him being the Managing Pharmacist and getting charged for that again is double-dipping.

Mr. Keegan requested that Exhibits 1-9 and the Declaration of Monica Segedy to be entered into the record.

President Park admitted.

Board discussion ensued.

Board Action:

Motion: President Park moved to make the Findings of Fact consistent with the Stipulated Facts.

Second: Krystal Freitas

Action: Passed unanimously (Zakariassen recused).

The Board discussed the Counts that the respondents may be guilty of.

Board Action:

Motion: Wayne Mitchell moved to find Joseph DeLallo guilty of all Counts One through Counts Three.

Second: Krystal Freitas

Action: Passed unanimously (Zakariassen recused).

The Board discussed the proposed discipline for Mr. DeLallo and CVS Pharmacy #4691.

Board Action:

Motion: President Park moved to discipline Joseph DeLallo's Certificate of Registration No. 18429 a fine of $3,000 for the violations, and CVS Pharmacy #4691 License No. PH02471 a fine of $4,000 for the violations.

Second: Wayne Mitchell

Action: Passed unanimously (Zakariassen recused).

Mr. Keegan requested the Board find that the attorney's fees and costs of $1,452.60 were reasonable, necessary, and actually incurred.

Board Action:

Motion: President Park moved to award the attorney's fees and costs of $1,452.60 on the basis that they were reasonable, necessary, and actually incurred.

Second: Krystal Freitas

Action: Passed unanimously (Zakariassen recused).

Board Action:

Motion: Gener Tejero moved to discipline Joseph DeLallo's Certificate of Registration No. 18429 and shall pay $500 to partially reimburse the Board for recoverable attorney's fees and investigative costs, and CVS Pharmacy #4691 License No. PH02471 shall pay $952.60 to partially reimburse the Board for recoverable attorney's fees and investigative costs.

Second: Krystal Freitas

Action: Passed unanimously (Zakariassen recused).

11. Application for Nevada Compounding Pharmacy License (NRS 639.230) – Appearance **(FOR POSSIBLE ACTION)**

Serologix, LLC – Las Vegas, NV

Michael Freudiger, Managing Pharmacist, and Lars Bell, Managing Partner, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Joe Dodge, Nevada Board of Pharmacy Inspector, provided background on the appearance and questioned the application's sterile compounding affidavit that was signed.

Mr. Bell requested that the sterile compounding affidavit be removed from the application.

Mr. Dodge questioned Serologix on the products that they intend to compound in Nevada, Mr. Freudiger's sterile compounding experience, and the policies and procedures of the company.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Nevada compounding pharmacy license for Serlogix, LLC pending a positive inspection.

Second: Wayne Mitchell

Action: Passed unanimously.

19. Applications for Controlled Substance Registration (NRS 453.226) – Appearance **(FOR POSSIBLE ACTION)**

B. Daisy de Guzman

Daisy de Guzman appeared and was sworn in by President Park prior to answering questions and offering testimony.

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, provided background on the appearance regarding a disclosure where she was a New Jersey Doctor that received monetary gifts from a marketing agent.

The Board discussed that the application does not have all her disclosure documents.

President Park asked if Ms. De Guzman would like to table her application so that she can provide Board staff with the proper documents.

Ms. De Guzman agreed.

President Park tabled application at Ms. De Guzman's request.

A. Jorge Burgos

Jorge Burgos appeared and was sworn in by President Park prior to answering questions and offering testimony.

Crane Pomerantz appeared as counsel on behalf of Mr. Burgos.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, provided background on the appearance which was tabled from the last Board Meeting due to not having all his disclosure documents. Dr. Burgos has submitted the necessary documentation which he has reviewed and sees no issues.

Dave Wuest, Executive Secretary for the Nevada Board of Pharmacy, confirmed that a temporary license was granted until his appearance before the Board.

Board discussion ensued.

Board Action:

Motion: Rolf Zakariassen moved to approve the Controlled Substance Registration for Jorge Burgos.

Second: Gener Tejero

Action: Passed unanimously.

14. Applications for Out-of-State Wholesalers License (NRS 639.233) Appearance **(FOR POSSIBLE ACTION)**

B. OxyGo HQ Florida LLC – Orlando, FL – Background Check Not Required – Manufacturer (NAC 639.593)(7)(d)

Steve Murphy, West Coast Sales Manager, appeared and was sworn in by President Park prior to answering questions and offering testimony.

President Park requested a Letter of Authorization for Mr. Murphy to speak on behalf of the company.

Gregory Zunino provided background on the application and questioned the disclosures regarding a cease and desist/citation due to unlicensed practice by the Nevada Board of Pharmacy and a pending litigation against OxyGo HQ Florida.

Mr. Murphy is not familiar with any of the disclosures.

President Park asked Mr. Murphy if he would like to table the application so that he can get more information on the disclosures or bring someone who would know more about it.

Mr. Murphy agreed.

President Park tabled the application at Mr. Murphy's request.

19. Applications for Controlled Substance Registration (NRS 453.226) – Appearance **(FOR POSSIBLE ACTION)**

C. Rachael Hueftle

Rachael Hueftle appeared and was sworn in by President Park prior to answering questions and offering testimony.

Dave Wuest provided background on the appearance and the disclosures regarding unlicensed practice and fraudulent prescriptions written under her license.

The Board questioned Ms. Hueftle on the measures that she has in place to ensure that her licenses are in compliance and to check for any fraudulent prescriptions written under her license.

Ms. Hueftle answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Controlled Substance Registration for Rachael Hueftle.

Second: Rolf Zakariassen

Action: Passed unanimously.

8. Applications for Nevada Medical, Devices, Equipment and Gases License (NAC 639.6944) – Appearance **(FOR POSSIBLE ACTION)**

B. Pacific Medical, Inc. – Carson City, NV
C. Pacific Medical, Inc. (Carson Tahoe) – Carson City, NV
D. Pacific Medical, Inc. (Northern Nevada) – Sparks, NV
E. Pacific Medical, Inc. – Reno, NV
F. Pacific Medical, Inc. (Renown) – Reno, NV
G. Pacific Medical, Inc. (St. Mary's) – Reno, NV

Justin Crandell, Director of OrthoLife, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Mark Weaver appeared as counsel on behalf of Pacific Medical, Inc.

Dave Wuest provided background on the appearance which stemmed from an inspection which led Board staff to find how Pacific Medical, Inc. was operating in Nevada which is not compliant with Nevada laws. Based on how the Board proceeds today, he will address these based on what they decide.

Mr. Crandell provided background on the business model to the Board and offered to work together to amend Nevada laws.

The Board questioned the business model.

Mr. Wuest clarified that the findings were not originated from a complaint but found during an inspection.

Board discussion ensued.

Board Action:

Motion: President Park moved to approve a temporary license for all six locations until the regulation change pending positive inspections. Pacific Medical, Inc. will need to work with Board staff on approved MDEG Administrators for each location and would need to disclose in their communications to patients that they have a choice to choose any medical product provider.

Gener Tejero wanted to mention that the company should have an MDEG Administrator backup just in case someone leaves to ensure coverage.

Second: Richard Tomasso

Action: Passed unanimously.

Richard Tomasso was excused from the Board Meeting at 2:10 PM.

10. Application for Nevada Pharmacy License (NRS 639.230) – Appearance **(FOR POSSIBLE ACTION)**

    Vital Care of Henderson – Henderson, NV

Nicholas Coulter, Managing Pharmacist, appeared and was sworn in by President Park prior to answering questions and offering testimony.

President Park disclosed that she knows Mr. Coulter but can participate in this matter fairly and without bias.

Dave Wuest provided background on the appearance. The company is requesting a Nevada pharmacy retail license to get started but will come back later when they are ready to do sterile compounding.

The Board questioned the application since Alberto Fernandez's Personal History Application is missing.

President Park requested a Letter of Authorization for Mr. Coulter to speak on behalf of the company.

Board discussion ensued.

Board Action:

Motion: President Park moved to approve Nevada pharmacy license for Vital Care of Henderson pending Letter of Authorization, Personal History Record for Alberto Fernandez, and a positive inspection. Board staff is authorized to review personal history record for Alberto Fernandez and approve application and if Board staff finds something concerning, they may bring the application before the Board for an appearance.

Second: Krystal Freitas

Action: Passed unanimously.

9. Applications for Out-of-State Medical, Devices, Equipment and Gases License (NAC 639.6944) – Appearance **(FOR POSSIBLE ACTION)**

Quest Health Solutions LLC – Santa Rosa, CA

Tammy Bowman, Office Manager, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Brett Kandt provided background the appearance and questioned Ms. Bowman's MDEG Administrator application disclosures regarding several arrests for drug paraphernalia, possession of a narcotic, shoplifting, and driving on a suspended license.

Ms. Bowman provided background and explained that she made mistakes in her past but has changed.

The Board questioned the business model of the company.

Ms. Bowman answered questions to the Board's satisfaction.

President Park requested a Letter of Authorization for Ms. Bowman to speak on behalf of the company.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Out-of-State Medical, Devices, Equipment and Gases License for Quest Health Solutions LLC pending Letter of Authorization.

Second: Rolf Zakariassen

Action: Passed unanimously.

14. Applications for Out-of-State Wholesalers License (NRS 639.233) Appearance **(FOR POSSIBLE ACTION)**

    D. Zimmer US, Inc. – Warsaw, IN – Background Check Not Required - Publicly Traded (NAC 639.593(7)(a))

Julia Lawson appeared as counsel on behalf of Zimmer US, Inc.

Gregory Zunino provided background on the appearance and the disclosure regarding two cease and desist/citations due to unlicensed practice that were sent by the Nevada Board of Pharmacy which were paid.

Ms. Lawson provided clarification and commented that the company is working to get licensed in the states required.

The Board questioned the business model.

Ms. Lawson answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Out-of-State Wholesaler License for Zimmer US, Inc.

Second: Wayne Mitchell

Action: Passed unanimously.

17. Applications for Pharmaceutical Technician in Training Registration (NAC 639.242) – Appearance. (**FOR POSSIBLE ACTION)**

    Anthony Radel

Anthony Radel appeared and was sworn in by President Park prior to answering questions and offering testimony.

Brett Kandt provided background on the appearance and the disclosures regarding charges of open lewdness and child abuse.

Mr. Radel provided clarification to Board on the charges as he was only trying to protect his son from bad dreams. He did complete the conditions of his charges.

The Board questioned why he wants to be a pharmaceutical technician-in-training.

Mr. Radel answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Pharmaceutical Technician-in-Training application for Anthony Radel.

Second: Wayne Mitchell

Action: Passed unanimously.

18. Petition for Reinstatement of Pharmacist Registration pursuant to NRS 639.257 – Appearance. **(FOR POSSIBLE ACTION)**

Paul Luke

Paul Luke appeared and was sworn in by President Park prior to answering questions and offering testimony.

Brett Kandt provided background on the appearance for a petition for reinstatement since the Board revoked his registration due to Mr. Luke getting disciplined for diversion.

Mr. Luke apologized and is ashamed of his actions. He has learned his lesson.

Board discussion ensued.

Board Action:

Motion: Rolf Zakariassen moved to reinstate Paul Luke's Pharmacist Registration No. 15314 pending submission of 45 continuing education credit hours.

Second: Krystal Freitas

Action: Passed unanimously.

19. Applications for Controlled Substance Registration (NRS 453.226) – Appearance **(FOR POSSIBLE ACTION)**

D. Kent Alan Swaine

Kent Alan Swaine appeared and was sworn in by President Park prior to answering questions and offering testimony.

Brett Kandt provided background on the appearance regarding Mr. Swaine requesting authority to prescribe Controlled Substances Schedule II.

Mr. Swaine provided background on his request as he needs it for his current employment.

Ms. Long provided background on his previous appearance before the Board and the conditions placed where he could prescribe Controlled Substances IV's and V's and buprenorphine only.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the modification to Kent Alan Swaine's restricted Certificate of Registration No. CS34350 to include Schedules II-V, and approved his application for a controlled substance registration for the 3760 Pecos Mcleod practice location for schedules II-V, subject to his compliance with the monitoring agreement and terms place upon his license No. 21803 to practice medicine by the Nevada State Board of Medical Examiners.

Second: Gener Tejero

Action: Passed unanimously.

14. Applications for Out-of-State Wholesalers License (NRS 639.233) Appearance **(FOR POSSIBLE ACTION)**

    A. AMO Sales and Services, Inc. – Irvine, CA – Background Check Not Required – Publicly Traded (NAC 639.593(7)(a))

Matt Foster appeared as counsel on behalf of AMO Sales and Services, Inc.

Gregory Zunino provided background on the appearance and disclosure regarding a cease and desist/citation due to unlicensed practice that was sent out by the Nevada Board of Pharmacy.

Mr. Foster confirmed that the fine has been paid to the Board.

The Board questioned the business model and the products being shipped into Nevada.

Mr. Foster answered questions to the Board's satisfaction.

Board discussion ensued.

Rolf Zakarissen commented that the Wholesaler Administrator's Application Sandor Palfi's hours do not seem possible.

Mr. Foster commented that they can correct the application.

Board Action:

Motion: Rolf Zakariassen moved to approve the Out-of-State Wholesaler License for AMO Sales and Services, Inc. pending the corrected Wholesaler Administrator application.

Second: Krystal Freitas

Action: Passed unanimously.

8. Applications for Nevada Medical, Devices, Equipment and Gases License (NAC 639.6944) – Appearance **(FOR POSSIBLE ACTION)**

A. Ab Medical LLC – Las Vegas, NV

Corrisa Girton, Administrator, and Blanca Barahona, Owner, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Brett Kandt provided background on the appearance.

The Board questioned the business model, Ms. Girton's experience, and Ms. Barahona's experience owning a business.

Ms. Girton and Ms. Barahona answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Nevada Medical, Devices, Equipment and Gases License for Ab Medical LLC.

Second: Wayne Mitchell

Action: Passed unanimously.

22. Executive Secretary Report:

A. Financial Report
B. Issuance of Temporary Licenses and Registrations
C. Change of Address Business List
D. Meetings with Other Health Care Regulatory Boards
E. COVID-19 Response
F. Licensing Software Update
G. Licensing Activities Report

H. PMP Integration
I. Citations & Fines issued pursuant to NRS 632.2895

Dave Wuest provided the Executive Secretary Report to the Board's satisfaction.

21. General Counsel Report. Note: The Board may exclude the public for a report on potential or existing litigation pursuant to NRS 241.015(3)(b)(2).

Brett Kandt provided the General Counsel Report to the Board's satisfaction.

12. Application for Out-of-State Pharmacy License (NRS 639.230) – Appearance – **(FOR POSSIBLE ACTION)**

Seven Hills Pharmacy, LLC – Sharonville, OH

This matter was continued to a future Board Meeting.

13. Application for Out-of-State Compounding Pharmacy License (NRS 639.230) – Appearance – **(FOR POSSIBLE ACTION)**

A. Brava NC LLC – Morrisville, NC

This matter was continued to a future Board Meeting.

B. Kings Park Slope, LLC – Brooklyn, NY

This matter was continued to a future Board Meeting.

C. Primera Professional Pharmacy – Sugar Land, TX

This matter was continued to a future Board Meeting.

D. Town Total Compounding Center – Woodbury, NY

This matter was continued to a future Board Meeting.

E. WP Pharma Labs, Inc. – Dallas, TX

This matter was continued to a future Board Meeting.

F. 1st Choice Pharmacy – Holiday, FL

This matter was continued to a future Board Meeting.

14. Applications for Out-of-State Wholesalers License (NRS 639.233) Appearance **(FOR POSSIBLE ACTION)**

C. STERRX, LLC – Plattsburgh, NY – Background Check Not Required - VAWD-Accredited (NAC 639.593(7)(c))

This matter was continued to a future Board Meeting.

15. Application for Out-of-State Outsourcing Facility (NRS 639.100) – Appearance (**FOR POSSIBLE ACTION**)

A. BPI Labs, LLC – Largo, FL

This matter was continued to a future Board Meeting.

B. Hikma Injectables USA Inc. – Dayton, NJ

This matter was continued to a future Board Meeting.

C. STERRX, LLC – Plattsburgh, NY

This matter was continued to a future Board Meeting.

24. Public Comment June 15, 2023, 3:58 PM

There was no public comment.

23. Date and Location of Next Scheduled Board Meeting:

September 6-7, 2023 – Las Vegas, NV

25. Adjournment

# 4

# 4A

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

**Non-Refundable $500 fee**

Rev (05/12/2022)

| | | |
|---|---|---|
| **Where is the facility located?** | ☐ Nevada | ■ Out-of-State |
| **[a]Is the business also a wholesaler? (NRS 639.016)** | ☐ Yes | ☒ No |

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient.** The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

| Type of Application (check applicable box) | | MDEG Business Type (check applicable box) |
|---|---|---|
| ■ New MDEG | * If making a change, provide current license number: | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9) |
| ☐ Ownership Change* | | ■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9) |
| ☐ Name Change* | | ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9) |
| ☐ Location Change* | M _____ | ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9) |

### Section 1: General Information

Facility Name: HEALTHCARE HD LLC

MDEG Physical Address: 1281 SAN CHRISTOPHER DR

City: DUNEDIN State: FL Zip: 34698-5334

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 727-216-6025 Website: https://healthcarehd.com/

Email: CREDENTIALING@HEALTHCAREHD.COM

Name of MDEG Administrator (NAC 639.694): caroline Fannin

| Entities the MDEG will Serve | Type of MDEG products that will be sold (check all applicable) |
|---|---|
| ■ Patients by prescriptions | ☐ Medical Gases** |
| ☐ Pharmacies[a] | ☐ Respiratory Equipment** |
| ☐ Practitioners[a] | ☐ Life-sustaining equipment** |
| ☐ Hospitals/Clinics[a] | ☐ Parenteral and Enteral Equipment** |
| ☐ Clinics[a] | ☐ Assistive Equipment |
| ☐ Wholesalers[a] | ■ Diabetic Supplies |
| ☐ Other business entities (specify)[a]: | ■ Orthotics and Prosthetics |
| | ■ Others: DME, UV LIGHT THERAPY, UROLOGICAL |
| This application is ONLY required if MDEG products will be sold to patients by prescription. | **These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954): |
| [a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov) | Name: _____ |
| | Telephone: _____ |

| Check the Days the Business will be Opened and provide the Hours of Operation | | | | |
|---|---|---|---|---|
| ☒ Mon: 09:00a-03:30p | ☒ Tue: 09:00a-03:30p | ☒ Wed: 09:00a-03:30p | ☒ Thurs: 09:00a-03:30p | ☒ Fri: 09:00a-03:30p |
| ☐ Sat: | ☐ Sun: | ☐ Holidays: | | |

| Section 2: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✔ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? | | ✔ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | ✔ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✔ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✔ |

**If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))**

MEDICARE - 7966760001

FLORIDA MEDICAID - 114304800

**Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)**

Name: _____ Credentials: _____ %: _____

Name: no / na Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

## Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

## Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: FLORIDA

Parent Company (if any): _____

Corporation/Organization Name: HEALTHCARE HD LLC

Mailing Address: 1281 SAN CHRISTOPHER DR

City: DUNEDIN State: FL Zip: 34698-5334

Telephone: 727-216-6025 Email: CREDENTIALING@HEALTHCAREHD.COM

Contact Person Name: CAROLINE FANNIN

## Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

## Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

| Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** | ✓ | ✓ | | |
| • **List of all general and limited partner names and their percent ownership (NAC 639.6942).** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**. | ✓ | ✓ | ✓ | ✓ |
| • **Medical products provider located** outside of this State **must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00). | ✓ | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/ | ✓ | ✓ | ✓ | ✓ |
| • [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/ | ✓ | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

CAROLINE FANNIN

Print Name of Authorized Person Submitting Application

Caroline Fannin

Original signature of Authorized Person (copies or stamps not accepted)

5/28/23

Date

| Board Use Only | Date Received: 7·3·23 | Amount: 500 check # 2011 |
|---|---|---|

# State of Florida
## Department of State

I certify from the records of this office that HEALTHCARE HD LLC is a limited liability company organized under the laws of the State of Florida, filed on May 7, 2020, effective May 7, 2020.

The document number of this limited liability company is L20000124557.

I further certify that said limited liability company has paid all fees due this office through December 31, 2022, that its most recent annual report was filed on April 21, 2022, and that its status is active.

*Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Seventh day of March, 2023*

*Secretary of State*

**Tracking Number: 5886913215CU**

**To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.**

**https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication**

View current license information at: Floridahealthfinder.gov

LICENSE #: 1315004
CERTIFICATE #: 25250

# State of Florida

AGENCY FOR HEALTH CARE ADMINISTRATION
DIVISION OF HEALTH QUALITY ASSURANCE

# Home Medical Equipment Provider

LICENSED

This is to confirm that HEALTHCARE HD LLC has complied with rules and regulations adopted by the State of Florida, Agency for Health Care Administration, as authorized in Chapter 400, Part VII and Chapter 408, Part II, Florida Statutes, and Chapter 59A-25, Florida Administrative Code, and is authorized to operate the following:

**HEALTHCARE HD LLC**
1281 San Christopher Dr
Dunedin, FL 34698
in the following counties:
ALL COUNTIES

EFFECTIVE DATE: 05/11/2022

EXPIRATION DATE: 05/10/2024

Simone Marstiller, Secretary
Division of Health Quality Assurance

ACORD®

# CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
10/07/2022

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

| | |
|---|---|
| PRODUCER<br>Glen Forbes Agency<br>903 W 1700 S<br>StateFarm Syracuse, UT 84075 | CONTACT NAME: Glen Forbes<br>PHONE (A/C, No, Ext): 801-779-2423 FAX (A/C, No): 801-779-4046<br>E-MAIL ADDRESS: glen@glenforbesagency.com |
| INSURED<br>Healthcare HD LLC<br>1281 SAN CHRISTOPHER DR<br>DUNEDIN, FL 346985334 | INSURER(S) AFFORDING COVERAGE — NAIC #<br>INSURER A : State Farm Fire and Casualty Company — 25143<br>INSURER B :<br>INSURER C :<br>INSURER D :<br>INSURER E :<br>INSURER F : |

**COVERAGES** **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

| INSR LTR | TYPE OF INSURANCE | ADDL INSR | SUBR WVD | POLICY NUMBER | POLICY EFF (MM/DD/YYYY) | POLICY EXP (MM/DD/YYYY) | LIMITS | | |
|---|---|---|---|---|---|---|---|---|---|
| | GENERAL LIABILITY | | | 47129F091820 | 09/18/2020 | 09/18/2023 | EACH OCCURRENCE | $ | 1,000,000 |
| | [X] COMMERCIAL GENERAL LIABILITY | | | | | | DAMAGE TO RENTED PREMISES (Ea occurrence) | $ | 500,000 |
| | [ ] CLAIMS-MADE [X] OCCUR | | | | | | MED EXP (Any one person) | $ | 10,000 |
| | | | | | | | PERSONAL & ADV INJURY | $ | |
| | | | | | | | GENERAL AGGREGATE | $ | 2,000,000 |
| | GEN'L AGGREGATE LIMIT APPLIES PER: | | | | | | PRODUCTS - COMP/OP AGG | $ | 2,000,000 |
| | [X] POLICY [ ] PRO-JECT [ ] LOC | | | | | | | $ | |
| | AUTOMOBILE LIABILITY | | | | | | COMBINED SINGLE LIMIT (Ea accident) | $ | |
| | ANY AUTO | | | | | | BODILY INJURY (Per person) | $ | |
| | ALL OWNED AUTOS / SCHEDULED AUTOS | | | | | | BODILY INJURY (Per accident) | $ | |
| | HIRED AUTOS / NON-OWNED AUTOS | | | | | | PROPERTY DAMAGE (Per accident) | $ | |
| | | | | | | | | $ | |
| | UMBRELLA LIAB [ ] OCCUR | | | | | | EACH OCCURRENCE | $ | |
| | EXCESS LIAB [ ] CLAIMS-MADE | | | | | | AGGREGATE | $ | |
| | DED [ ] RETENTION $ | | | | | | | $ | |
| | WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N | | | 98CMH5404 | 08/30/2021 | 08/30/2023 | [ ] WC STATU-TORY LIMITS [ ] OTH-ER | | |
| | ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICE/MEMBER EXCLUDED? [ ] N/A | | | | | | E.L. EACH ACCIDENT | $ | 1000000 |
| | (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below | | | | | | E.L. DISEASE - EA EMPLOYEE | $ | 1000000 |
| | | | | | | | E.L. DISEASE - POLICY LIMIT | $ | 1000000 |
| | | | | | | | | | |

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (Attach ACORD 101, Additional Remarks Schedule, if more space is required)

**CERTIFICATE HOLDER**

NATIONAL SUPPLIER CLEARINGHOUSE~AG~-495
PO BOX 100142
COLUMBIA SC 29202-3412

**CANCELLATION**

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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# CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 01/18/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

| PRODUCER | CONTACT NAME: Hunter Barcomb | |
|---|---|---|
| Brown & Brown of Florida, Inc.<br>83 Park Place Blvd, Suite 101<br>Clearwater FL 33759 | PHONE (A/C, No, Ext): (813) 226-1309 | FAX (A/C, No): |
| | E-MAIL ADDRESS: hunter.barcomb@bbrown.com | |
| | INSURER(S) AFFORDING COVERAGE | NAIC # |
| | INSURER A : Lloyd's of London | 32727 |
| INSURED<br>Healthcare HD, LLC<br>1281 San Christopher Dr<br>Dunedin FL 34698 | INSURER B : | |
| | INSURER C : | |
| | INSURER D : | |
| | INSURER E : | |
| | INSURER F : | |

**COVERAGES** **CERTIFICATE NUMBER:** 23-24 Master **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

| INSR LTR | TYPE OF INSURANCE | ADDL INSD | SUBR WVD | POLICY NUMBER | POLICY EFF (MM/DD/YYYY) | POLICY EXP (MM/DD/YYYY) | LIMITS | |
|---|---|---|---|---|---|---|---|---|
| A | COMMERCIAL GENERAL LIABILITY<br>[X] CLAIMS-MADE [ ] OCCUR<br>[X] Professional Liability<br>GEN'L AGGREGATE LIMIT APPLIES PER:<br>[X] POLICY [ ] PRO-JECT [ ] LOC<br>[ ] OTHER: | | | TMP000090-01 | 01/13/2023 | 01/13/2024 | EACH OCCURRENCE | $ 1,000,000 |
| | | | | | | | DAMAGE TO RENTED PREMISES (Ea occurrence) | $ |
| | | | | | | | MED EXP (Any one person) | $ |
| | | | | | | | PERSONAL & ADV INJURY | $ |
| | | | | | | | GENERAL AGGREGATE | $ 2,000,000 |
| | | | | | | | PRODUCTS - COMP/OP AGG | $ |
| | | | | | | | | $ |
| | AUTOMOBILE LIABILITY<br>[ ] ANY AUTO<br>[ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS<br>[ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY | | | | | | COMBINED SINGLE LIMIT (Ea accident) | $ |
| | | | | | | | BODILY INJURY (Per person) | $ |
| | | | | | | | BODILY INJURY (Per accident) | $ |
| | | | | | | | PROPERTY DAMAGE (Per accident) | $ |
| | | | | | | | | $ |
| | [ ] UMBRELLA LIAB [ ] OCCUR<br>[ ] EXCESS LIAB [ ] CLAIMS-MADE<br>[ ] DED [ ] RETENTION $ | | | | | | EACH OCCURRENCE | $ |
| | | | | | | | AGGREGATE | $ |
| | | | | | | | | $ |
| | WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N<br>ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [ ] N/A<br>(Mandatory In NH)<br>If yes, describe under DESCRIPTION OF OPERATIONS below | | | | | | [ ] PER STATUTE [ ] OTH-ER | |
| | | | | | | | E.L. EACH ACCIDENT | $ |
| | | | | | | | E.L. DISEASE - EA EMPLOYEE | $ |
| | | | | | | | E.L. DISEASE - POLICY LIMIT | $ |

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Home Medical Equipment

**CERTIFICATE HOLDER**

Healthcare HD, LLC
1281 San Christopher Dr
Dunedin FL 34698

**CANCELLATION**

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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The ACORD name and logo are registered marks of ACORD

1281 San Christopher Drive,
Dunedin FL 34689-5334
Phone : 727-216-6025
Fax: 727-216-0982

Healthcare HD LLC
NPI: 1316563737
EIN: 85-1145521

To: Provider Enrollment

See below for HEALTHCARE HD LLC's disclosure of ownership information. Please let us know if you have any questions or concerns.

Disclosing Entity
Name: HEALTHCARE HD LLC
Address: 1281 SAN CHRISTOPHER DR, DUNEDIN FL 34698-5334
NPI: 1316563737
FEIN: 85-1145521

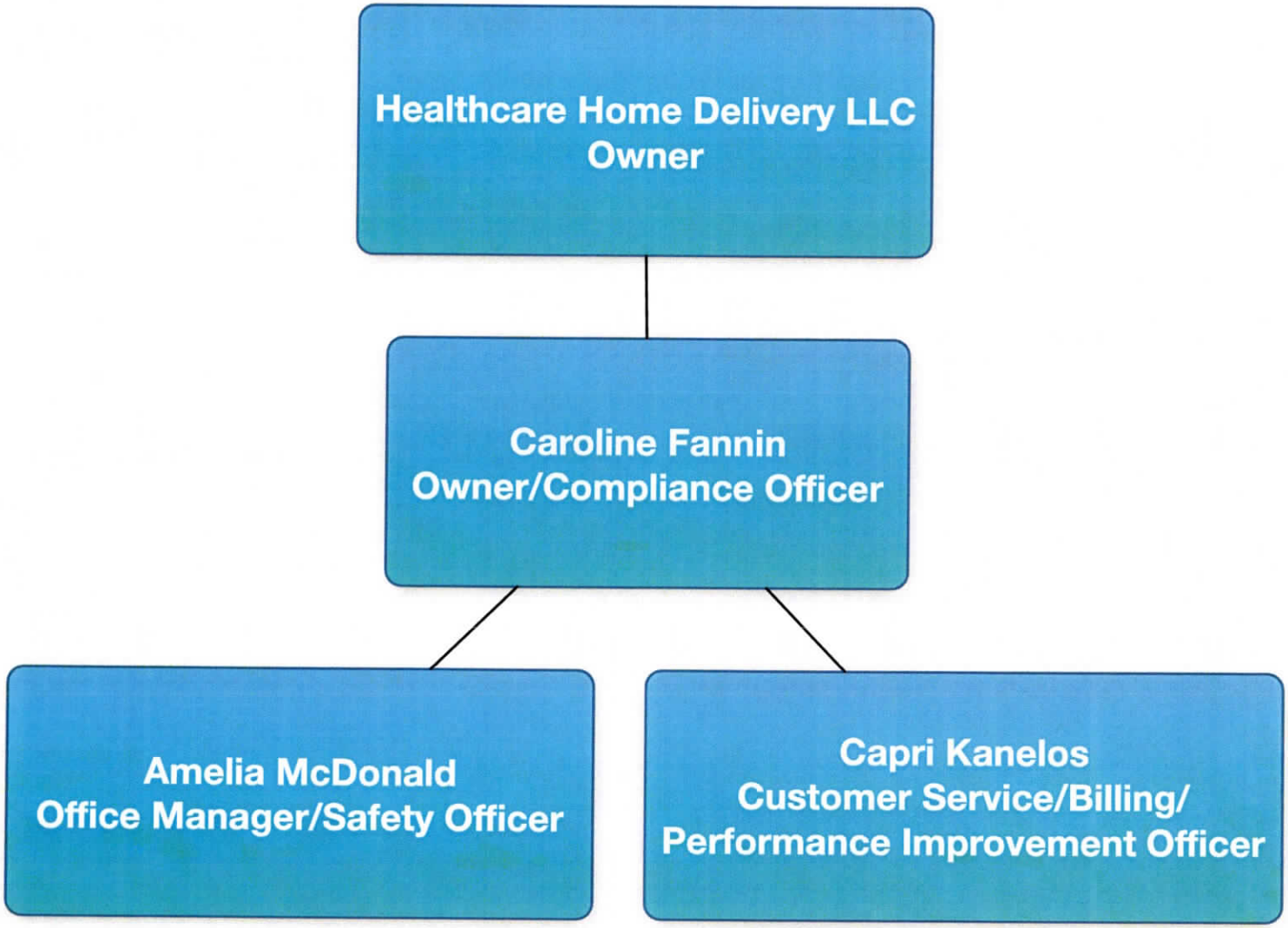
Ownership 1: INDIVIDUAL Percentage: 95%
Owner Name: CAROLINE FANNIN
Role: PRESIDENT DOB: [redacted]
SSN: [redacted]
Address: [redacted] BROOKLANDS WAY, DELAND FL 32724-7753

Ownership 2: ENTITY/ORGANIZATION Percentage: 5%
Owner Name: HEALTHCARE HOME DELIVERY LLC
FEIN: 83-1266751
Address: 334 E LAKE RD, SUITE 165, PALM HARBOR FL 34685

Caroline Fannin

Caroline Fannin - President
cfannin@healthcarehd.com
Office: 727-216-6025
FAX: 727-216-9082

# Healthcare HD Organizational Chart



CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

MEDICARE

NOVITAS SOLUTIONS

May 02, 2023

HEALTHCARE HD LLC
ATTN CAROLINE FANNIN
306 BROOKLANDS WAY
DELAND FL 32724

Reference #: 3230748019

Dear HEALTHCARE HD LLC,

Novitas Solutions, Inc. approved your reactivation application.

**Medicare Enrollment Information**

Supplier Legal Business Name (LBN): HEALTHCARE HD LLC
Doing Business As (DBA): N/A
Physical Address Location: 1281 SAN CHRISTOPHER DR, DUNEDIN, FL, 346985334
Supplier Type: MEDICAL SUPPLY COMPANY
National Provider Identifier (NPI): 1316563737
Provider Transaction Access Number (PTAN): 7966760001
PTAN Effective Date: MARCH 15, 2023
Participation Status: PARTICIPATING PROVIDER

Your PTAN is the authentication element for all inquiries to customer service representatives (CSRs), written inquiry units, and the interactive voice response (IVR) system.

To file claims electronically, please contact the Common Electronic Data Exchange (CEDI) Contractor at www.ngscedi.com or (866) 311-9184.

Subscribe to receive timely listserv messages regarding Medicare billing policies at:

- Jurisdiction A – Noridian Healthcare Solutions, med.noridianmedicare.com/web/jadme
- Jurisdiction B – CGS, www.cgsmedicare.com

IRS DEPARTMENT OF THE TREASURY
INTERNAL REVENUE SERVICE
CINCINNATI OH 45999-0023

Date of this notice: 05-22-2020

Employer Identification Number:
85-1145521

Form: SS-4

Number of this notice: CP 575 B

HEALTHCARE HD LLC
CAROLINE FANNIN MBR
1281 SAN CHRISTOPHER DR
DUNEDIN, FL 34698

For assistance you may call us at:
1-800-829-4933

IF YOU WRITE, ATTACH THE
STUB AT THE END OF THIS NOTICE.

## WE ASSIGNED YOU AN EMPLOYER IDENTIFICATION NUMBER

Thank you for applying for an Employer Identification Number (EIN). We assigned you EIN 85-1145521. This EIN will identify you, your business accounts, tax returns, and documents, even if you have no employees. Please keep this notice in your permanent records.

When filing tax documents, payments, and related correspondence, it is very important that you use your EIN and complete name and address exactly as shown above. Any variation may cause a delay in processing, result in incorrect information in your account, or even cause you to be assigned more than one EIN. If the information is not correct as shown above, please make the correction using the attached tear off stub and return it to us.

Based on the information received from you or your representative, you must file the following form(s) by the date(s) shown.

| Form 1065 | 03/15/2021 |
|---|---|

If you have questions about the form(s) or the due date(s) shown, you can call us at the phone number or write to us at the address shown at the top of this notice. If you need help in determining your annual accounting period (tax year), see Publication 538, *Accounting Periods and Methods*.

We assigned you a tax classification based on information obtained from you or your representative. It is not a legal determination of your tax classification, and is not binding on the IRS. If you want a legal determination of your tax classification, you may request a private letter ruling from the IRS under the guidelines in Revenue Procedure 2004-1, 2004-1 I.R.B. 1 (or superseding Revenue Procedure for the year at issue). Note: Certain tax classification elections can be requested by filing Form 8832, *Entity Classification Election*. See Form 8832 and its instructions for additional information.

A limited liability company (LLC) may file Form 8832, *Entity Classification Election*, and elect to be classified as an association taxable as a corporation. If the LLC is eligible to be treated as a corporation that meets certain tests and it will be electing S corporation status, it must timely file Form 2553, *Election by a Small Business Corporation*. The LLC will be treated as a corporation as of the effective date of the S corporation election and does not need to file Form 8832.

To obtain tax forms and publications, including those referenced in this notice, visit our Web site at www.irs.gov. If you do not have access to the Internet, call 1-800-829-3676 (TTY/TDD 1-800-829-4059) or visit your local IRS office.

# The Board of Certification / Accreditation, International

Owings Mills, Maryland, USA

# Accredited Facility

Practice limited to DMEPOS supplier categories:

DM05,DM06,M01,DM02,OR03,PD06,S01,PD09

The Board of Certification / Accreditation attests that the Facility named below complies with all requirements for facility accreditation.

**Healthcare HD LLC**
**DBA: Healthcare HD LLC**
**1281 San Christopher Dr.**
**Dunedin, FL 34698-5334**

This accreditation is awarded for meeting the professional standards of BOC, together with all the honors, rights, privileges and responsibilities in pursuit of our mission to assure patients, physicians, professional organizations, the public-at-large, and government agencies and representatives of the competence and professionalism of BOC-Accredited Facilities.
In witness whereof, we have affixed the seal of the Board and subscribed our names in acknowledgement.

Matthew Gruskin, MBA, BOCO, BOCPD, Credentialing Director

Claudia Zacharias, MBA, CAE, President & CEO

**S62533**
Facility Number

**August 2024**
Accredited Through

Accredited Since: **2021**

BOC is a CMS deemed accrediting organization.

This accreditation is the property of BOC — the certificate holder agrees to abide by the BOC / CMS standards.

Form **W-9**
(Rev. October 2018)
Department of the Treasury
Internal Revenue Service

# Request for Taxpayer Identification Number and Certification

▶ Go to *www.irs.gov/FormW9* for instructions and the latest information.

**Give Form to the requester. Do not send to the IRS.**

Print or type. See Specific Instructions on page 3.

1 Name (as shown on your income tax return). Name is required on this line; do not leave this line blank.
**HEALTHCARE HD LLC**

2 Business name/disregarded entity name, if different from above
**HEALTHCARE HD LLC**

3 Check appropriate box for federal tax classification of the person whose name is entered on line 1. Check only one of the following seven boxes.

☐ Individual/sole proprietor or single-member LLC ☐ C Corporation ☐ S Corporation ☐ Partnership ☐ Trust/estate

☑ Limited liability company. Enter the tax classification (C=C corporation, S=S corporation, P=Partnership) ▶ P

**Note:** Check the appropriate box in the line above for the tax classification of the single-member owner. Do not check LLC if the LLC is classified as a single-member LLC that is disregarded from the owner unless the owner of the LLC is another LLC that is not disregarded from the owner for U.S. federal tax purposes. Otherwise, a single-member LLC that is disregarded from the owner should check the appropriate box for the tax classification of its owner.

☐ Other (see instructions) ▶

4 Exemptions (codes apply only to certain entities, not individuals; see instructions on page 3):

Exempt payee code (if any) _____

Exemption from FATCA reporting code (if any) _____

*(Applies to accounts maintained outside the U.S.)*

5 Address (number, street, and apt. or suite no.) See instructions.
**1281 SAN CHRISTOPHER DR**

Requester's name and address (optional)

6 City, state, and ZIP code
**DUNEDIN, FL 34698-5334**

7 List account number(s) here (optional)

## Part I Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. The TIN provided must match the name given on line 1 to avoid backup withholding. For individuals, this is generally your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the instructions for Part I, later. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN*, later.

**Note:** If the account is in more than one name, see the instructions for line 1. Also see *What Name and Number To Give the Requester* for guidelines on whose number to enter.

**Social security number**
| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | – | | | – | | | | |

or

**Employer identification number**
| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8 | 5 | – | 1 | 1 | 4 | 5 | 5 | 2 | 1 |

## Part II Certification

Under penalties of perjury, I certify that:

1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me); and
2. I am not subject to backup withholding because: (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding; and
3. I am a U.S. citizen or other U.S. person (defined below); and
4. The FATCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is correct.

**Certification instructions.** You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and generally, payments other than interest and dividends, you are not required to sign the certification, but you must provide your correct TIN. See the instructions for Part II, later.

**Sign Here** Signature of U.S. person ▶ Carolin Lann Date ▶ **05/01/2023**

## General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

**Future developments.** For the latest information about developments related to Form W-9 and its instructions, such as legislation enacted after they were published, go to *www.irs.gov/FormW9*.

## Purpose of Form

An individual or entity (Form W-9 requester) who is required to file an information return with the IRS must obtain your correct taxpayer identification number (TIN) which may be your social security number (SSN), individual taxpayer identification number (ITIN), adoption taxpayer identification number (ATIN), or employer identification number (EIN), to report on an information return the amount paid to you, or other amount reportable on an information return. Examples of information returns include, but are not limited to, the following.

- Form 1099-INT (interest earned or paid)
- Form 1099-DIV (dividends, including those from stocks or mutual funds)
- Form 1099-MISC (various types of income, prizes, awards, or gross proceeds)
- Form 1099-B (stock or mutual fund sales and certain other transactions by brokers)
- Form 1099-S (proceeds from real estate transactions)
- Form 1099-K (merchant card and third party network transactions)
- Form 1098 (home mortgage interest), 1098-E (student loan interest), 1098-T (tuition)
- Form 1099-C (canceled debt)
- Form 1099-A (acquisition or abandonment of secured property)

Use Form W-9 only if you are a U.S. person (including a resident alien), to provide your correct TIN.

*If you do not return Form W-9 to the requester with a TIN, you might be subject to backup withholding. See* What is backup withholding, *later.*

DUNEDIN
Home of Honeymoon Island

# CITY OF DUNEDIN

"Dedicated to Quality Service"
P.O. BOX 1348
DUNEDIN, FL 34697-1348
(727) 298-3210

**HEALTHCARE HD**
**1281 SAN CHRISTOPHER DR**
**DUNEDIN FL 34698**

THE FOLLOWING MUST BE POSTED IN A CONSPICUOUS PLACE

## CITY OF DUNEDIN LOCAL BUSINESS TAX RECEIPT

Conduct of any business subject to zoning restriction. The issuance of this Local Business Tax Receipt does not authorize the taxpayer to operate in violation of any City ordinance, law or regulation. Any change in location or ownership must be recorded with the City's Local Business Tax Section. Issuance of the Local Business Tax Receipt is in no way intended as an approval or disapproval of the taxpayer's competence or skill. Business taxes are non-refundable.

| | | |
|---|---|---|
| Business Name: | HEALTHCARE HD | Phone No: |
| Location Address: | 1281 SAN CHRISTOPHER DR | |
| Classification: | MERCHANT (C) | |
| Business Tax No: | 23-00020205 | |
| Issued: | August 08, 2022 | Expires: September 30, 2023 |
| Total: | $0.00 | |
| Comments: | | |

*FOLD HERE*

**THE FOLLOWING APPLIES TO BUSINESSES THAT ARE LOCATED IN THE CITY OF DUNEDIN:**

**TRANSFERS:** Many Local Business Tax Receipts are transferable from one owner to another or from one location to another. If you wish to transfer this Local Business Tax Receipt to another owner/location, please contact the City's Local Business Tax Receipt Section for information.

**CHANGES:** Changes in business name or address or mailing name or address, as well as changes or additions to the business, activity, service or work may require additional applications and/or fees and taxes. Please contact the City's Local Business Tax Receipt Section for information prior to making changes.

**PENALTIES:** All Local Business Tax Receipts are due and payable before October 1st of each year and expire on September 30th of the succeeding year. Those Local Business Tax Receipts not renewed by October 1st are considered delinquent and are subject to a delinquency penalty of 10% for October, plus an additional 5% penalty for each month thereafter until paid, but not to exceed 25% of the Local Business Tax due.

A 25% penalty is imposed on any person engaged in any new business, occupation or profession without first obtaining a Local Business Tax Receipt.

Any person who engages in any business, occupation, or profession whose classification is required to pay a Local Business Tax, who does not pay the required Local Business Tax within 150 days after the initial notice of tax due, and who does not obtain the required Local Business Tax Receipt is subject civil actions and penalties, including court cost, reasonable attorneys' fees, additional administrative cost incurred as a result of collection efforts, and a penalty of $250.00.

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

### Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG HEALTHCARE HD LLC MDEG License # (if applicable) _____

Physical Address 1281 SAN CHRISTOPHER DR

City DUNEDIN State FL Zip 34698-5334

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 727-216-6025 Website https://healthcarehd.com/

Licensing Company Email CREDENTIALING@HEALTHCAREHD.COM

### Section 2: Personal Information

First CAROLINE Middle _____ Last FANNIN

Alias(es, nicknames, name changes, etc.) XXXX Rubenbauer

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted] BROOKLANDS WAY

City DELAND State FL Zip 32724

Telephone [redacted] Email CFANNING@HEALTHCAREHD.COM

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | ✓ | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| EMBRY-RIDDLE AERONAUTICAL UNIVERSITY | | 89-92 | |
| **Address** | **City** | **State** | **Zip** |
| 1 AEROSPACE BLVD | DAYTONA | FL | 32114 |
| **Diploma/Degree obtained, if any** | | | |
| BS AVIATION | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| SUFFOLK COUNTY COMMUNITY COLLEGE | | 85-88 | |
| **Address** | **City** | **State** | **Zip** |
| 1001 CROOKED HILL RD | BRENTWOOD | NY | 1171 |
| **Diploma/Degree obtained, if any** | | | |
| ASSOCIATE IN BUSINESS | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| HAUPPAUGE HIGH SCHOOL | | 81-84 | |
| **Address** | **City** | **State** | **Zip** |
| 500 LINCOLN BLVD | HAUPPAUGE | NY | 11788 |
| **Diploma/Degree obtained, if any** | | | |
| HIGH SCHOOL DIPLOMA | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |
| **School Name** | | **From - To (MM/YY – MM/YY** | |
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| | [redacted]BROOKLANDS WAY | DELAND | FL | 32724-7753 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |

**Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)**

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| HEALTHCARE HD LLC | | 05/20 | |
| **Business Address** | **City** | **State** | **Zip** |
| 1281 SAN CHRISTOPHER DR | DUNEDIN | FL | 34698-5334 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| 727-216-6025 | PRESIDENT - OWNER | 30120 | |
| **Description of Duties** | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state? | | ✔ |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline. | | ✔ |

**Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>**

This is in response to Question # _____. **Provide all the following *<u>where applicable</u>*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Caroline Lamm
Original Signature (electronic, copies or stamps not accepted)

5/28/23
Date

I, CAROLINE FANNIN, **certify that as the MDEG Administrator for**

HEALTHCARE HD LLC,

**that I (initial that you have read and meet the following requirements):**

1. X Have a high school diploma or its equivalent;
2. X Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. X Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. X Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

CAROLINE FANNIN

Print Name (First, Last)

Caroline Fannin

Original Signature (electronic, copies or stamps not accepted)

5/28/23

Date

| Board Use Only | Date Received: |
|---|---|

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/18/2023)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site HEALTHCARE HD LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 1281 SAN CHRISTOPHER DR

City DUNEDIN State FL Zip 34698-5334

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 727-216-6025 Website https://healthcarehd.com/

Licensing Company Email CREDENTIALING@HEALTHCAREHD.COM

**Section 2: Personal Information**

First CAROLINE Middle _____ Last FANNIN

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted] BROOKLANDS WAY

City DELAND State FL Zip 32724-7753

Telephone [redacted] Email CFANNIN@HEALTHCAREHD.COM

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| EMBRY-RIDDLE AERONAUTICAL UNIVERSITY | | | 89-92 | |
| Address | | City | State | Zip |
| 1 AEROSPACE BLVD | | DAYTONA | FL | 32114 |
| Diploma/Degree obtained, if any | | | | |
| BS AVIATION | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| SUFFOLK COUNTY COMMUNITY COLLEGE | | | 85-88 | |
| Address | | City | State | Zip |
| 1001 CROOKED HILL RD | | BRENTWOOD | NY | 11717 |
| Diploma/Degree obtained, if any | | | | |
| ASSOCIATE IN BUSINESS | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| HAUPPAUGE HIGH SCHOOL | | | 81-84 | |
| Address | | City | State | Zip |
| 500 LINCOLN BLVD | | HAUPPAUGE | NY | 11788 |
| Diploma/Degree obtained, if any | | | | |
| HIGH SCHOOL DIPLOMA | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |
| School Name | | | From - To (MM/YY – MM/YY | |
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| | [redacted] BROOKLANDS WAY | DELAND | FL | 32724-7753 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| HEALTHCARE HD LLC | | | 05/20 - CURRENT |
| **Business Address** | **City** | **State** | **Zip** |
| 1281 SAN CHRISTOPHER DR | DUNEDIN | FL | 34698-5334 |
| **Phone** | **Title** | | |
| 727-216-6025 | PRESIDENT - OWNER | | |
| **Description of Duties** | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # _____. **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| | | | | |
| Reason/Charge | | | | |
| | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| | | | | |
| Name of Business/Industry/Entity | | | | |
| | | | | |

**Provide explanation below:**

Caroline Jann
Original Signature (electronic, copies or stamps not accepted)

5/28/23
Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

CAROLINE FANNIN

Print Name (First, Last)

Caroline Fannin — 5/28/23

Original Signature (electronic, copies or stamps not accepted) — Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Florida, ss. County of Volusia

I, Caroline Fannin, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Caroline Fannin — 6/5/2023

**Original Signature** — **Date**

Subscribed and Sworn to before me this 5TH day of June 2023.

Yolanda Colon. Yolanda Colon

**Notary Public Signature**

NOTARY PUBLIC
YOLANDA COLON
Notary Public, State of Florida
Commission# HH231799
My comm. expires Feb. 21, 2026

**(Seal)**

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

### Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler HEALTHCARE HD LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 1281 SAN CHRISTOPHER DR

City DUNEDIN State FL Zip 34698-5334

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 727-216-6025 Website https://healthcarehd.com/

Licensing Company Email CREDENTIALING@HEALTHCAREHD.COM

### Section 2: Personal Information

First CAROLINE Middle _____ Last FANNIN

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]BROOKLANDS WAY

City DELAND State FL Zip 32724-7753

Telephone 727-216-6025 Email CFANNIN@HEALTHCAREHD.COM

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| EMBRY-RIDDLE AERONAUTICAL UNIVERSITY | | 89-92 | |
| **Address** | **City** | **State** | **Zip** |
| 1 AEROSPACE BLVD | DAYTONA | FL | 32114 |
| Diploma/Degree obtained, if any | | | |
| BS AVIATION | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| SUFFOLK COUNTY COMMUNITY COLLEGE | | 85-88 | |
| **Address** | **City** | **State** | **Zip** |
| 1001 CROOKED HILL RD | BRENTWOOD | NY | 11717 |
| Diploma/Degree obtained, if any | | | |
| ASSOCIATE IN BUSINESS | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| HAUPPAUGE HIGH SCHOOL | | 81-84 | |
| **Address** | **City** | **State** | **Zip** |
| 500 LINCOLN BLVD | HAUPPAUGE | NY | 11788 |
| Diploma/Degree obtained, if any | | | |
| HIGH SCHOOL DIPLOMA | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| | [redacted] BROOKLANDS WAY | DELAND | FL | 32724-7753 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| HEALTHCARE HD LLC | | | 05/20 - CURRENT | |
| **Business Address** | | **City** | **State** | **Zip** |
| 1281 SAN CHRISTOPHER DR | | DUNEDIN | FL | 34698-5334 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 727-216-6025 | PRESIDENT - OWNER | | 30120 | |
| **Description of Duties** | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # _____. **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| | | | | |
| Reason/Charge | | | | |
| | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| | | | | |
| Name of Business/Industry/Entity | | | | |
| | | | | |

**Provide explanation below:**

Caroline Lamm

Original Signature (electronic, copies or stamps not accepted)

5/28/23

Date

I, CAROLINE FANNIN, **certify that as the designated representative for**

HEALTHCARE HD LLC,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. X I am at least 21 years of age;
3. X I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. X I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. X I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. X I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. X I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

CAROLINE FANNIN

Print Name (First, Last)

Caroline Fannin

Original Signature (electronic, copies or stamps not accepted)

5/28/23

Date

NOTARY

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

CAROLINE FANNIN

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/5/2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Florida, ss. County of Volusia

I, Caroline Fannin, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

6/5/2023

**Date**

Subscribed and Sworn to before me this 5th day of June 2023.

Yolanda Colon

**Notary Public Signature**

YOLANDA COLON
Notary Public, State of Florida
Commission# HH231799
My comm. expires Feb. 21, 2026

**(Seal)**

# 4B

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

**Non-Refundable $1,000 Fee**

Rev (08/17/2022)

| **Where is the facility located?** L000362 | ☐ Nevada ☑ Out-of-State |
|---|---|

| **Type of Application (check applicable box)** | | **Wholesaler Business Type (check applicable box)** |
|---|---|---|
| ☑ New Wholesaler<br>☐ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH _____ | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: QuVa Pharma, Inc.

Physical Address: 4717 East Hilton Avenue Suite 400

City: Phoenix State: AZ Zip: 85034

Mailing Address (if different from physical address): 4717 East Hilton Avenue Suite 400

City: Phoenix State: AZ Zip: 85034

Telephone: 888-339-0874 Website: www.quvapharma.com

Name of Designated Representative (DR): Donna Kohut

Licensing Company Email: michelle.kostroun@quvapharma.com DR Email: donna.kohut@quvapharma.com

| **Entities the Wholesaler will Serve (✓ all applicable)** | **Products to be Handled or Wholesaled (✓ all applicable)** | **Type of Wholesaling (✓ all applicable)** |
|---|---|---|
| ☐ Pharmacies | ☑ Dangerous Drugs | ☐ Manufacturer |
| ☐ Practitioners | ☐ Controlled Substances | ☐ Repacker |
| ☑ Hospitals | ☐ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ☐ Wholesalers | ☐ Others: | ☑ Warehouse 3PL activity of QuVa Pharma, Inc. 503B products (prescription drugs sold to hospitals) |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ☐ Others: | | ☐ Others: |

| **Section 2: History of Company** | **Yes** | **No** |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✓ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | ✓ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | ✓ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✓ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✓ |

Not applicable

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

Date

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: N/A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

**Section 4: Publicly Traded Corporation**

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: Delaware

Parent Company (if any): QuVa Pharma Holdings, Inc.

Corporation/Organization Name: QuVa Pharma, Inc.

Mailing Address: 3 Sugar Creek

City: Sugar Land State: Texas Zip: 77478

Telephone: 888-339-0874 Email: peter.jenkins@quvapharma.com

Contact Person Name: Peter Jenkins

**Section 6: Partnership**

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

**Section 7: Sole Owner**

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | ✓ |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | | ✓ |
| 1. Copy of FDA registration<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** N/A | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** | | ✓ | | |
| • **List of all partners and their percent ownership.** N/A | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** N/A | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) N/A | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

QuVa Pharma, Inc.

Facility Name

Peter Jenkins

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

6/14/2023

Date

| Board Use Only | Date Received: 6.20.23 | Amount: 1000.00 CK-30123 |
|---|---|---|

June 16, 2023

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

To Whom it May Concern:

QuVa Pharma, Inc. (the "Company") provides the list of Corporate Officers.

1) **Stuart Hinchen – Chief Executive Officer**
   Corporate Address: 3 Sugar Creek Center Blvd, Suite 250
   Sugar Land, Texas 77478
   Business Phone: 888-339-0874

2) **Peter Jenkins - Chief Development Officer/Treasurer**
   Corporate Address: 3 Sugar Creek Center Blvd, Suite 250
   Sugar Land, Texas 77478
   Business Phone: 888-339-0874

3) **Ryan Sullivan – Chief Legal Officer, General Counsel and Secretary**
   Corporate Address: 3 Sugar Creek Center Blvd, Suite 250
   Sugar Land, Texas 77478
   Business Phone: 888-339-0874

4) **Nir Naor – Chief Financial Officer**
   Corporate Address: 3 Sugar Creek Center Blvd, Suite 250
   Sugar Land, Texas 77478
   Business Phone: 888-339-0874

5) **Scott Hirsch – Chief Operations Officer**
   Corporate Address: 3 Sugar Creek Center Blvd, Suite 250
   Sugar Land, Texas 77478
   Business Phone: 888-339-0874

If you have any additional questions, please contact me at michelle.kostroun@quvapharma.com or 254-933-4453.

Sincerely,

Michelle Kostroun – Regulatory and Compliance
QuVa Pharma, Inc.

QuVa PHARMA

# Shareholder Information

QuVa Pharma Holdings is the 100% shareholder of QuVa Pharma, Inc.

3 Sugar Creek Center Blvd, Suite 250
Sugar Land, TX 77478

888.339.0874
QuVaPharma.com

# Delaware

The First State



*I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "QUVA PHARMA, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTIETH DAY OF DECEMBER, A.D. 2022.*

*AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.*

*AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "QUVA PHARMA, INC." WAS INCORPORATED ON THE TWENTY-EIGHTH DAY OF MAY, A.D. 2015.*

*AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.*

Jeffrey W. Bullock, Secretary of State

5755668 8300

SR# 20224330528

Authentication: 205151360

Date: 12-20-22

You may verify this certificate online at corp.delaware.gov/authver.shtml

# Arizona State Board of Pharmacy

Physical Address: 1110 W. Washington St., Suite 260, Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
(P): 602-771-2727 (F): 602-771-2749 www.azpharmacy.gov


## CERTIFICATION OF ARIZONA STATE BOARD OF PHARMACY PERMIT FOR THE ENTITY LISTED BELOW :

**This document is not a license/permit but serves as the primary source of verification.**

| | |
|---|---|
| **Name :** | QuVa Pharma, Inc. |
| **Address :** | 4717 East Hilton Avenue Suite # 400 Phoenix AZ 85034 |
| **License No :** | L000362 |
| **Permit Type :** | Third Party Logistics |
| **Sub Type :** | 3PL |
| **Date Issued :** | 06/08/2023 |
| **Expiration Date :** | 10/31/2023 |
| **Status :** | OPEN |
| **Discipline :** | No |

Kam Gandhi

**Kam Gandhi**

**ARIZONA STATE BOARD OF PHARMACY**
**P.O. Box 18520 Phoenix, AZ 85005**
**602-771-ASBP (2727)**
**FAX: 602-771-2749**
**http://www.azpharmacy.gov**

Receipt Date: 06/15/2022
Receipt Number: 2022128971
Receipt Amount $: 1000.00

# Third Party Logistics - 3PL

**PERMIT NO**
**L000362**

**EXPIRES**
**10/31/2023**

Issued to : QuVa Pharma, Inc.
QuVa Pharma Holdings, Inc.
5920 SOUTH GENERAL BRUCE DRIVE TEMPLE, TX 76502

QuVa Pharma, Inc.
4717 EAST HILTON AVENUE SUITE # 400
PHOENIX, AZ 85034

**EXECUTIVE DIRECTOR**

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : QuVa Pharma, Inc.
LICENSE NUMBER : L000362
EXPIRES : 10/31/2023

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

## Important Information

**LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)**

- Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
- You are required by law to notify the Board of any home address and/or employment change within 10 business days

**PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)**

- Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
- In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.
- Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

# NEVADA STATE BOARD OF PHARMACY

**985 Damonte Ranch Pkwy Suite 206**
**Reno, NV 89521**
**(775) 850-1440**
**Fax: (775) 850-1444**

## PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 6213029625

Application/License No. _____

QuVa Pharma, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 4717 East Hilton Avenue Suite 400 Phoenix, AZ 85034 (Address of Applicant/Principal), as PRINCIPAL, and United States Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of Delaware (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 305 MADISON AVENUE, MORRISTOWN, NJ 07960 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on May 11, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 11th day of May, 2023.

APPLICANT/PRINCIPAL
QuVa Pharma, Inc.
COMPANY

Authorized Representative

SURETY
United States Fire Insurance Company

Surety Company's Representative

Gentry Stewart, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness, India Buxton

Witness, Sarah Murtha

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

**POWER OF ATTORNEY**
**UNITED STATES FIRE INSURANCE COMPANY**
**PRINCIPAL OFFICE - MORRISTOWN, NEW JERSEY**

**79560**

**KNOW ALL MEN BY THESE PRESENTS**: That United States Fire Insurance Company, a corporation duly organized and existing under the laws of the state of Delaware, has made, constituted and appointed, and does hereby make, constitute and appoint:

Aimee R. Perondine, Bethany Stevenson, Donna M. Planeta, Joshua Sanford, Samuel E. Begun, Melissa J. Stanton, Nicholas Turecamo, Kathryn Pryor, Michelle Anne McMahon, Alexis R. Apostolidis, Brendan William Fletcher, Cassandra Baez, Jacqueline Rose Susco, Rebecca M. Josephson, Amanda Pierina D'Angelo, Eric Strba, Gentry Stewart, Jennifer Gail Godere

each, its true and lawful Attorney(s)-In-Fact, with full power and authority hereby conferred in its name, place and stead, to execute, acknowledge and deliver: Any and all bonds and undertakings of surety and other documents that the ordinary course of surety business may require, and to bind United States Fire Insurance Company thereby as fully and to the same extent as if such bonds or undertakings had been duly executed and acknowledged by the regularly elected officers of United States Fire Insurance Company at its principal office, in amounts or penalties not exceeding: **UNLIMITED.**

This Power of Attorney limits the act of those named therein to the bonds and undertakings specifically named therein, and they have no authority to bind United States Fire Insurance Company except in the manner and to the extent therein stated.

This Power of Attorney is granted pursuant to Article IV of the By-Laws of United States Fire Insurance Company as now in full force and effect, and consistent with Article III thereof, which Articles provide, in pertinent part:

Article IV, Execution of Instruments - Except as the Board of Directors may authorize by resolution, the Chairman of the Board, President, any Vice-President, any Assistant Vice President, the Secretary, or any Assistant Secretary shall have power on behalf of the Corporation:

(a) to execute, affix the corporate seal manually or by facsimile to, acknowledge, verify and deliver any contracts, obligations, instruments and documents whatsoever in connection with its business including, without limiting the foregoing, any bonds, guarantees, undertakings, recognizances, powers of attorney or revocations of any powers of attorney, stipulations, policies of insurance, deeds, leases, mortgages, releases, satisfactions and agency agreements;
(b) to appoint, in writing, one or more persons for any or all of the purposes mentioned in the preceding paragraph (a), including affixing the seal of the Corporation.

Article III, Officers, Section 3.11, Facsimile Signatures. The signature of any officer authorized by the Corporation to sign any bonds, guarantees, undertakings, recognizances, stipulations, powers of attorney or revocations of any powers of attorney and policies of insurance issued by the Corporation may be printed, facsimile, lithographed or otherwise produced. In addition, if and as authorized by the Board of Directors, dividend warrants or checks, or other numerous instruments similar to one another in form, may be signed by the facsimile signature or signatures, lithographed or otherwise produced, of such officer or officers of the Corporation as from time to time may be authorized to sign such instruments on behalf of the Corporation. The Corporation may continue to use for the purposes herein stated the facsimile signature of any person or persons who shall have been such officer or officers of the Corporation, notwithstanding the fact that he may have ceased to be such at the time when such instruments shall be issued.

**IN WITNESS WHEREOF**, United States Fire Insurance Company has caused these presents to be signed and attested by its appropriate officer and its corporate seal hereunto affixed this 10th day of March, 2016.

**UNITED STATES FIRE INSURANCE COMPANY**

Anthony R. Slimowicz, President

State of New Jersey}
County of Morris }

On this 10th day of March 2016, before me, a Notary public of the State of New Jersey, came the above named officer of United States Fire Insurance Company, to me personally known to be the individual and officer described herein, and acknowledged that he executed the foregoing instrument and affixed the seal of United States Fire Insurance Company thereto by the authority of his office.

**SONIA SCALA**
**NOTARY PUBLIC OF NEW JERSEY**
**MY COMMISSION EXPIRES 3/25/2024 No. 2163686**

Sonia Scala (Notary Public)

I, the undersigned officer of United States Fire Insurance Company, a Delaware corporation, do hereby certify that the original Power of Attorney of which the foregoing is a full, true and correct copy is still in force and effect and has not been revoked.

**IN WITNESS WHEREOF**, I have hereunto set my hand and affixed the corporate seal of United States Fire Insurance Company on the 11th day of May 2023

**UNITED STATES FIRE INSURANCE COMPANY**

Peter M. Quinn, Senior Vice President

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

**Section 1: Pharmacy/Wholesaler Information**

Name of Pharmacy/Wholesaler QuVa Pharma , Inc.

Pharmacy/Wholesaler License # (if applicable) L000362

Physical Address 4717 East Hilton Avenue Suite 400

City Phoenix State AZ Zip 85034

Mailing Address (if different from physical address) 4717 East Hilton Avenue Suite 400

City Phoenix State AZ Zip 85034

Telephone 888-339-0874 Website www.quvapharma.com

Licensing Company Email michelle.kostroun@quvapharma.com

**Section 2: Personal Information**

First Donna Middle _____ Last Kohut

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address 4717 East Hilton Avenue Suite400

City Phoenix State AZ Zip 85034

Telephone [redacted] Email donna.kohut@quvapharma.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | X |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| | | | |
|---|---|---|---|
| School Name: Villanova University | | From - To (MM/YY – MM/YY): 1980 – 1983 | |
| Address: 800 Lancaster Avenue | City: Villanova | State: PA | Zip: 19085 |
| Diploma/Degree obtained, if any: Master of Arts, Mathematics | | | |
| School Name: Temple University | | From - To (MM/YY – MM/YY): 1976 – 1980 | |
| Address: 1801 North Broad Street | City: Philadelphia | State: PA | Zip: 19122 |
| Diploma/Degree obtained, if any: Bachelor of Fine Arts, Dance Performance | | | |
| School Name: Plymouth Whitemarsh High School | | From - To (MM/YY – MM/YY): 1972 – 1976 | |
| Address: 201 E. Germantown Pike | City: Plymouth Mtg | State: ~~PA~~ PA | Zip: 19462 |
| Diploma/Degree obtained, if any: | | | |
| School Name | | From - To (MM/YY – MM/YY) | |
| Address | City | State | Zip |
| Diploma/Degree obtained, if any | | | |
| School Name | | From - To (MM/YY – MM/YY | |
| Address | City | State | Zip |
| Diploma/Degree obtained, if any | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 04/17 – 06/23 | [redacted] Belle Park Drive | Houston | TX | 77072 |
| 06/15 – 03/17 | [redacted] Park One Drive | Sugarland | TX | 77478 |
| 12/00 – 05/15 | [redacted] N. 16th St, [redacted] | Phoenix | AZ | 85020 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| QuVa Pharma,Inc. | | | 08/15 - Present | |
| Business Address | | City | State | Zip |
| 1075 West Park One Drive Suite 100 | | Sugar Land | TX | 77478 |
| Phone | Title | | Number of Employed Hours | |
| 888-339-0874 | Vice President | | 16000 | |
| Description of Duties | | | | |
| Oversight of sterile products and distribution. | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| | | | | |
| Phone | Title | | Number of Employed Hours | |
| | | | | |
| Description of Duties | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| | | | | |
| Phone | Title | | Number of Employed Hours | |
| | | | | |
| Description of Duties | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| | | | | |
| Phone | Title | | Number of Employed Hours | |
| | | | | |
| Description of Duties | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| | | | | |
| Phone | Title | | Number of Employed Hours | |
| | | | | |
| Description of Duties | | | | |
| | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✓ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✓ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✓ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✓ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| | | | | |
| Reason/Charge | | | | |
| | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| | | | | |
| Name of Business/Industry/Entity | | | | |
| | | | | |

**Provide explanation below:**

N/A dk 06/09/2023

Donna Fokut
Original Signature (electronic, copies or stamps not accepted)

06/09/2023
Date

I, Donna Kohut, **certify that as the designated representative for** QuVa Pharma, Inc., **that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. dk I am at least 21 years of age;
3. dk I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. dk I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. dk I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. dk I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. dk I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Donna Kohut

Print Name (First, Last)

Donna Kohut

Original Signature (electronic, copies or stamps not accepted)

06/09/2023

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Donna Kohut
Print Name (First, Last)

Donna Kohut — 06/12/2023
Original Signature (electronic, copies or stamps not accepted) — Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Arizona, ss. County of Maricopa

I, Donna Kohut, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Donna Kohut — 06/12/2023
**Original Signature** — **Date**

Subscribed and Sworn to before me this 12 day of June 2023

ALEXIS LONG
Notary Public - State of Arizona
MARICOPA COUNTY
Commission # 642967
Expires December 26, 2026

**Notary Public Signature**

**(Seal)**

QuVa PHARMA

# List of Employees

Donna Kohut – Designated Representative

June 26, 2023

Mark Sedar
Nevada State Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, NV 89521

RE: Exemption from fingerprint submissions for Designated Representative and Officers per NAC-639-593 Section 7 for a single manufacturer.

Hello Mark.

As per our conversation on June 20, 2023, QuVa Pharma, Inc. located at 4717 East Hilton Avenue, Suite 400, Phoenix, Arizona, 85034, would be exempt from submitting fingerprints as defined in Arizona rulebook under section 7 of NAC-639-593 (attachment 1).

Specifically, QuVa Pharma, Inc. facility located at 4717 East Hilton Avenue Suite 400, Phoenix, Arizona 85034 will serve as a Third-party logistics provider for compounded 503 B preparations manufactured at the QuVa Pharma, Inc. Sugar Land, Texas, Temple, Texas and Bloomsbury, New Jersey sites. The QuVa Pharma, Inc. Labeler code is 70092. Please see the FDA statement attached (attachment 2).

These products will be sent to hospitals and clinics in Nevada and other states provided that appropriate licensure is obtained.

Please let me know if you need any additional information. I can be reached via email at michelle.kostroun@quvapharma.com or phone number 254-933-4453.

Sincerely,

Michelle Kostroun

Michelle Kostroun
QuVa Pharma, Inc.
Regulatory Compliance Licensing

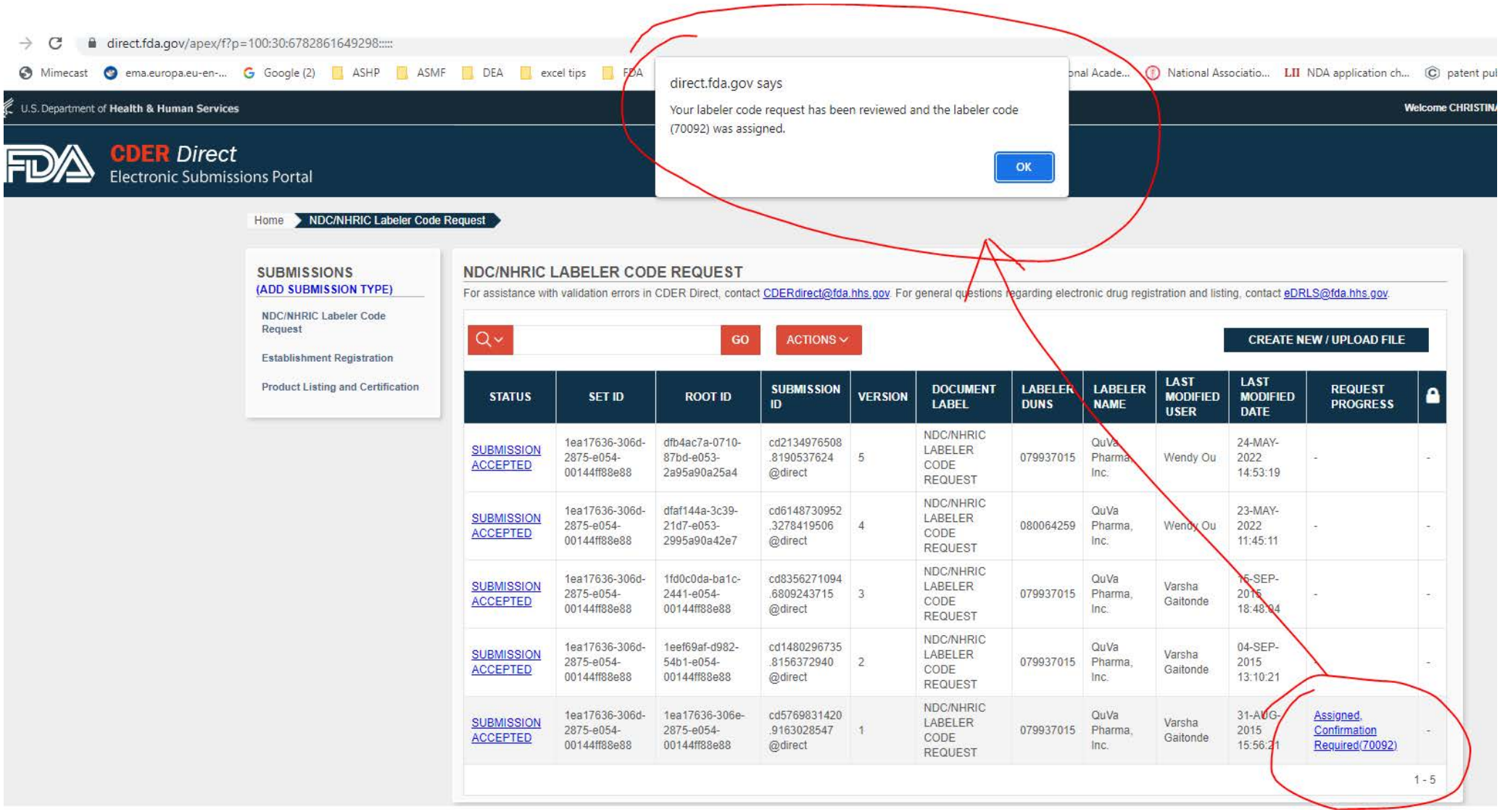
# Attachment 1

# NAC 639.593 Section 7

7. Unless the Board otherwise requires, a wholesaler is not required to submit fingerprints pursuant to subsection 6 if:
   (a) The wholesaler's securities are publicly traded and regulated by the Securities Exchange Act of 1934, as amended, 15 U.S.C. §§ 78a et seq.;
   (b) The wholesaler is owned by a corporation whose securities are publicly traded and regulated by the Act;
   (c) The wholesaler is accredited by the National Association of Boards of Pharmacy under the Verified-Accredited Wholesale Distributors program;
   (d) The wholesaler is a manufacturer of prescription drugs; or
   (e) The wholesaler is a facility that distributes prescription drugs manufactured by a single manufacturer.

   (Added to NAC by Bd. of Pharmacy, eff. 7-16-92; A by R013-01, 11-1-2001; R049-04, 2-28-2005; R218-05, 5-4-2006; R051-07, 12-4-2007)

# Attachment 2


direct.fda.gov/apex/f?p=100:30:6782861649298::::
Mimecast
ema.europa.eu-en-...
Google (2)
ASHP
ASMF
DEA
excel tips
FDA
National Associatio...
NDA application ch...
patent pul
direct.fda.gov says
Your labeler code request has been reviewed and the labeler code (70092) was assigned.
OK
U.S. Department of Health & Human Services
Welcome CHRISTIN
CDER Direct
Electronic Submissions Portal
Home
NDC/NHRIC Labeler Code Request
SUBMISSIONS
(ADD SUBMISSION TYPE)
NDC/NHRIC Labeler Code Request
Establishment Registration
Product Listing and Certification
NDC/NHRIC LABELER CODE REQUEST
For assistance with validation errors in CDER Direct, contact CDERdirect@fda.hhs.gov. For general questions regarding electronic drug registration and listing, contact eDRLS@fda.hhs.gov.
GO
ACTIONS
CREATE NEW / UPLOAD FILE
STATUS
SET ID
ROOT ID
SUBMISSION ID
VERSION
DOCUMENT LABEL
LABELER DUNS
LABELER NAME
LAST MODIFIED USER
LAST MODIFIED DATE
REQUEST PROGRESS
SUBMISSION ACCEPTED
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cd2134976508.8190537624@direct
5
NDC/NHRIC LABELER CODE REQUEST
079937015
QuVa Pharma, Inc.
Wendy Ou
24-MAY-2022 14:53:19
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NDC/NHRIC LABELER CODE REQUEST
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23-MAY-2022 11:45:11
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3
NDC/NHRIC LABELER CODE REQUEST
079937015
QuVa Pharma, Inc.
Varsha Gaitonde
15-SEP-2015 18:48:04
SUBMISSION ACCEPTED
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cd1480296735.8156372940@direct
2
NDC/NHRIC LABELER CODE REQUEST
079937015
QuVa Pharma, Inc.
Varsha Gaitonde
04-SEP-2015 13:10:21
SUBMISSION ACCEPTED
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cd5769831420.9163028547@direct
1
NDC/NHRIC LABELER CODE REQUEST
079937015
QuVa Pharma, Inc.
Varsha Gaitonde
31-AUG-2015 15:56:21
Assigned, Confirmation Required(70092)
1 - 5

# 4C

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

**Non-Refundable $1,000 Fee**

Rev (08/17/2022)

| **Where is the facility located?** | | ☐ Nevada ☒ Out-of-State |
|---|---|---|
| **Type of Application (check applicable box)** | | **Wholesaler Business Type (check applicable box)** |
| ☐ New Wholesaler<br>☒ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH WH03113 | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: Albireo Pharma, Inc.

Physical Address: 53 State St., 19th floor

City: Boston State: MA Zip: 02109

Mailing Address (if different from physical address): 53 State St., 19th Floor

City: Boston State: MA Zip: 02109

Telephone: (617) 679-8500 Website: www.albireopharma.com

Name of Designated Representative (DR): Kalin Kantchev

Licensing Company Email: distlicense@albireopharma.com DR Email: kalin.kantchev@albireopharma.com

| **Entities the Wholesaler will Serve (✓ all applicable)** | **Products to be Handled or Wholesaled (✓ all applicable)** | **Type of Wholesaling (✓ all applicable)** |
|---|---|---|
| ☐ Pharmacies | ☒ Dangerous Drugs | ☐ Manufacturer |
| ☐ Practitioners | ☐ Controlled Substances | ☐ Repacker |
| ☐ Hospitals | ☐ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ☐ Wholesalers | ☐ Others: | ☐ Warehouse |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ☒ Others: Specialty Pharmacies, Specialty Distributors | | ☒ Others: Virtual Manufacturer |

| **Section 2: History of Company** | **Yes** | **No** |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | x |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | x |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | x |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | x |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | x |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| | | | | |
| Reason/Charge | | | | |
| | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| | | | | |
| Name of Business/Industry/Entity | | | | |
| | | | | |

**Provide explanation below:**

COMMONWEALTH OF MASSACHUSETTS

Kalin Kantcheva

personally appeared before me, the undersigned notary public, and proved to me his/her identity through satisfactory evidence, which were Drivers License and acknowledged he/she signed the foregoing instrument voluntarily for its stated purpose on this 19 day of April, 2023

Notary Public

JAMES S. SARDELLA
NOTARY PUBLIC
Commonwealth of Massachusetts
My Commission Expires
March 15, 2030

Original Signature (electronic, copies or stamps not accepted)

19 Apr 2023

Date

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: See Attached

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

**Section 4: Publicly Traded Corporation**

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: DE

Parent Company (if any): Ipsen Biopharmaceuticals Inc

Corporation/Organization Name: Albireo Pharma, Inc.

Mailing Address: 53 State St., 19th Floor

City: Boston State: MA Zip: 02109

Telephone: 617 679 5600 Email: emery.popoloski@ipsen.com

Contact Person Name: Elliot Beimel

**Section 6: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

**Section 7: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | x |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | x | |
| 1. Copy of FDA registration<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** | | ✓ | | |
| • **List of all partners and their percent ownership.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner **owning more than 10% of the business stocks/shares**. Access form at http://bop.nv.gov/Services/newapps/Business/ | | NA ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** | ✓ | NA ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ | ✓ | NA ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). | ✓ | NA ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | NA ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | NA ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Albireo Pharma, Inc.
Facility Name

Kalin Kantchev
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

19 APR 2023
Date

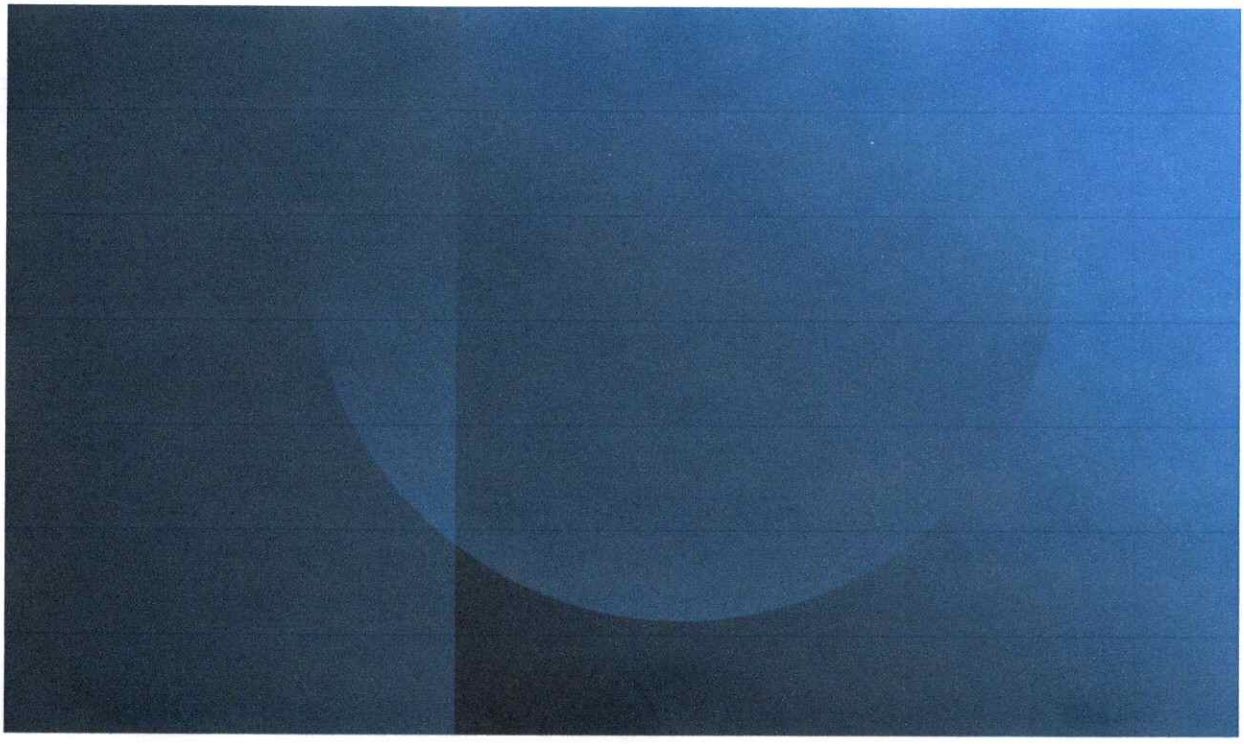
COMMONWEALTH OF MASSACHUSETTS

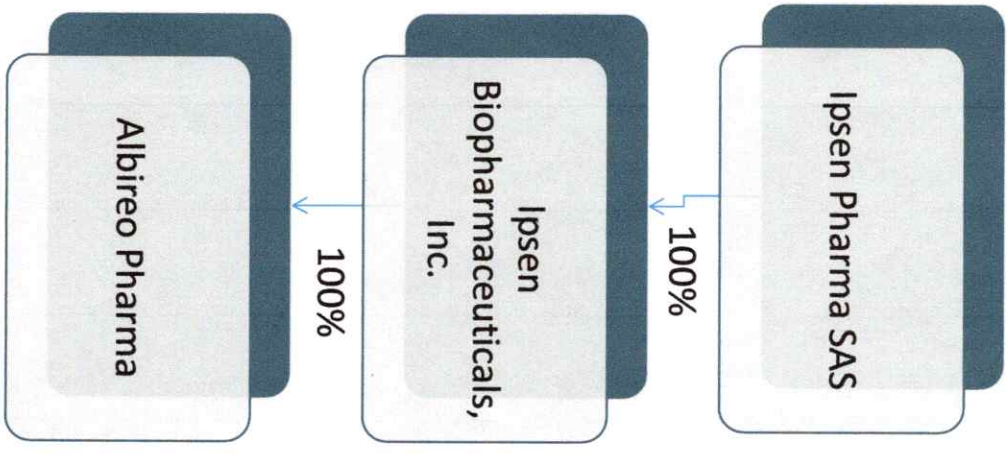
Kalin Kantchev personally appeared before me, the undersigned notary public, and proved to me his/her identity through satisfactory evidence, which were Driver's License and acknowledged he/she signed the foregoing instrument voluntarily for its stated purpose on this 19 day of April, 2023

Notary Public

JAMES S. SARDELLA
NOTARY PUBLIC
Commonwealth of Massachusetts
My Commission Expires
March 15, 2030

| Board Use Only | Date Received: 5-8-23 | Amount: 1000.00 CK - 18396 |
|---|---|---|




Ipsen Pharma SAS
100%
Ipsen Biopharmaceuticals, Inc.
100%
Albireo Pharma

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

# National Drug Code Directory

Current through April 24, 2023

**You have searched Finished drug products**

**Search Results:** *'albireo'*

Back to Search Page () | Search Again ()

CSV | Excel

Display 50 records per page

Search for text in the table:

| Proprietary Name | NDC Package Code | Strength | Dosage Form | Route | Appl. No. | Labeler Name | Product NDC | Nonproprietary Name | Substance Name | Product Type Name | Start Marketing Date | End Marketin Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + BYLVAY | 74528-020-01 | 200 ug/1 | CAPSULE, COATED PELLETS | ORAL | NDA215498 | Albireo Pharma, Inc. | 74528-020 | odevixibat | ODEVIXIBAT | HUMAN PRESCRIPTION DRUG | 07/20/2021 | N/A |
| + BYLVAY | 74528-040-01 | 400 ug/1 | CAPSULE, COATED PELLETS | ORAL | NDA215498 | Albireo Pharma, Inc. | 74528-040 | odevixibat | ODEVIXIBAT | HUMAN PRESCRIPTION DRUG | 07/20/2021 | N/A |
| + BYLVAY | 74528-060-01 | 600 ug/1 | CAPSULE, COATED PELLETS | ORAL | NDA215498 | Albireo Pharma, Inc. | 74528-060 | odevixibat | ODEVIXIBAT | HUMAN PRESCRIPTION DRUG | 07/20/2021 | N/A |
| + BYLVAY | 74528-120-01 | 1200 ug/1 | CAPSULE, COATED PELLETS | ORAL | NDA215498 | Albireo Pharma, Inc. | 74528-120 | odevixibat | ODEVIXIBAT | HUMAN PRESCRIPTION DRUG | 07/20/2021 | N/A |

Showing 1 to 4 of 4 entries Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)

See also: Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

## Company/Ownership Information

Albireo Pharma, Inc.
53 State St., 19th Floor
Boston, MA 02109
P: 857-254-5555
E-mail: distlicense@Albireopharma.com

**Tax ID: 90-0136863**
State of Formation: Delaware
Date Incorporated: **12/08/2003**

Albireo Pharma, Inc. is a privately held company owned by Ipsen Biopharmaceuticals Inc. which is owned by Ipsen Pharma SAS and is a publicly traded company on the foreign stock exchange.

## Officers

**Eliot Beimel, VP, Finance North America**
Business Address: One Main Street, 7th Floor, Cambridge, MA 02142
P: 781-382-5799 E-mail: distlicense@Albireopharma.com

**Jennifer Benenson, SVP, NA General Counsel**
Business Address: One Main Street, 7th Floor, Cambridge, MA 02142
P: 201-396-3769 E-mail: distlicense@Albireopharma.com

**Kalin Kantchev, Sr. Manager Supply Chain**
Business Address: 53 State St., 19th Floor, Boston, MA 02109
P: 857-254-5555
E-mail: distlicense@Albireopharma.com

## Description of Operations

Albireo Pharma, Inc. is a biopharmaceutical company focused on the development of novel bile acid modulators to treat rare pediatric and adult liver diseases, and other adult liver diseases and disorders. We have deep expertise in bile acid biology and a pipeline of clinical and nonclinical programs. Albireo is currently developing novel bile acid modulators to treat rare pediatric and adult liver diseases.

Albireo Pharma, Inc. ("Albireo") is a Virtual Manufacturer located at 53 State St., 19th floor, Boston, MA 02109. Albireo's hours of operation are 9:00am-5:00pm, M-F, Eastern Standard Time.

Albireo Pharma, Inc. is a privately held company owned by Ipsen Biopharmaceuticals Inc., which is owned by Ipsen Pharma SAS and is a publicly traded company on the foreign stock exchange.

## Contract Manufacturer

Albireo uses the following contract manufacturers to produce product. At no time does any contract manufacturer own Albireo product, contract with Albireo customers, invoice or sell Albireo product.

Patheon France S.A.S
40 Boulevard de Champaret
Bourgoin Jallieu, France 38 300
FEIN: 3004468553

Anderson Brecon, Inc. (PCI)
4545 Assembly Dr
Rockford, IL 61109
FEIN: 1421377

Product Name: Bylvay
Labeler Code: 74528

## Third Party Logistics

Albireo products are distributed to customers by their third-party logistics provider ("3PL"), Integrated Commercialization Solutions, Inc. (ICS). Albireo utilizes the following ICS location for storage and distribution of their product:

Integrated Commercialization Solutions, Inc.
167 International Blvd., Suite 550
Brooks, KY 40109
Contact: Michael Lamb
502-955-5100
michael.lamb@absg.com

# Delaware

The First State



*I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ALBIREO PHARMA, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRTIETH DAY OF MARCH, A.D. 2023.*

*AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.*

*AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "ALBIREO PHARMA, INC." WAS INCORPORATED ON THE EIGHTH DAY OF DECEMBER, A.D. 2003.*

*AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.*

Jeffrey W. Bullock, Secretary of State

3736631 8300

SR# 20231232661

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203046006

Date: 03-30-23

THE COMMONWEALTH OF MASSACHUSETTS

**DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM**

Massachusetts Controlled Substance Registration

In accordance with the provision of Massachusetts General Laws, Chapter 94C, issues the registration of Virtual Drug Manufacturer or Virtual Drug Distributor Controlled Substance Registration to:

ALBIREO PHARMA, INC.
53 STATE STREET, 19TH FLOOR
BOSTON, MA 02109

Margret R. Cooke
Commissioner - Department of Public Health

Registration Number: MA0000670

Type: Virtual Manufacturer

Issue Date: 04/24/2023

Expiration Date: 05/27/2024

COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH

Massachusetts Office of Health and Human Services (EOHHS)

Health Professions License Verification Site

Home Page > Profile > MA0000670 - ALBIREO PHARMA, INC.

**License Information**

| | |
|---|---|
| **License Type:** | Virtual Drug Manufacturer or Virtual Drug Distributor Controlled Substance Registration |
| **License Number:** | MA0000670 |
| **Status:** | Current |
| **Organization Name:** | ALBIREO PHARMA, INC. |
| **Expiration Date:** | May 27, 2024 |
| **Address:** | 53 STATE STREET 19TH FLOOR BOSTON, MA 02109 |

**Compliance Actions/Fines**

There are no public compliance actions or fines against this license/registration record.

<< Back to Search Page

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 29th day of June, 20 23.

APPLICANT/PRINCIPAL
Albireo Pharma, Inc

See attached PoA signature
Authorized Representative

SURETY COMPANY
Hartford Fire Insurance Company

Surety Company's Representative

Shelby Russell, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Lori A. Wright

Witness Rachel A. Chaveriat

Countersigned by:

N/A
Nevada Resident Agent

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

## PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 20BSBGH2401

Application/License No. WH03113

Albireo Pharma, Inc, doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 53 State Street, Boston, MA 02109, as PRINCIPAL, and Hartford Fire Insurance Company, a corporation organized under the laws of the state of CT and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Hartford Plaza, Hartford, CT 06155 as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on June 29, 2023.

(Applicant/Principal; Address of Applicant/Principal; Surety Company; State of Incorporation; Address of Surety; Effective Date)

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

# POWER OF ATTORNEY

*Direct Inquiries/Claims to:*
THE HARTFORD
BOND, T-11
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
*call:* **888-266-3488** *or fax:* **860-757-5835**

**KNOW ALL PERSONS BY THESE PRESENTS THAT:**

**Agency Name:** MARSH USA INC
**Agency Code:** 20-246454

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [X] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [X] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois**, a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast,** a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut, (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint, ***up to the amount of*** Unlimited :

Loretta M. Jones, Andrea Allman, Rachel A. Chaveriat, Meri Damron, Lisa Frye, Sandra King, Michelle Lute-Heatherly, Amanda L. Mills, Vicki Nobinger, Leslie Patterson, Bonnie Rice, Shelby Russell, Carolyn E. Wheeler, Carrie Wright, Lori A. Wright of KNOXVILLE, Tennessee

their true and lawful Attorney(s)-in-Fact, each in their separate capacity if more than one is named above, to sign its name as surety(ies) only as delineated above by ☒, and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

**In Witness Whereof**, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Shelby Wiggins

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

**STATE OF FLORIDA**
**COUNTY OF SEMINOLE** } ss. Lake Mary

On this 20th day of May, 2021, before me personally came Joelle LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Jessica Ciccone
My Commission HH 122280
Expires June 20, 2025

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of June 29, 2023.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

### Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Albireo Pharma, Inc.

Pharmacy/Wholesaler License # (if applicable) WHO3113

Physical Address 53 State St., 19th floor

City Boston State MA Zip 02109

Mailing Address (if different from physical address) 53 State St., 19th Floor

City Boston State MA Zip 02109

Telephone (617) 679-8500 Website www.albireopharma.com

Licensing Company Email distlicense@albireopharma.com

### Section 2: Personal Information

First Kalin Middle Kantchev Last Kantchev

Alias(es, nicknames, name changes, etc.) n/a

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 53 State St., 19th Floor

City Boston State MA Zip 02109

Telephone [redacted] Email kalin.kantchev@albireopharma.com

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | X |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Address | City | State | Zip |
| Diploma/Degree obtained, if any | | | |

| School Name | MIT and edX | From - To (MM/YY – MM/YY) | Sep2018- Mar2019 |
|---|---|---|---|
| Address | City | State | Zip |
| Diploma/Degree obtained, if any | Micromasters Certificate in Supply Chain Management | | |

| School Name | Northeastern University | From - To (MM/YY – MM/YY) | Jan2013-Dec2013 |
|---|---|---|---|
| Address: 360 Huntington Ave | City: Boston | State: MA | Zip: 02115 |
| Diploma/Degree obtained, if any | Graduate Certificate in Supply Chain Management | | |

| School Name | Bernard Baruch College (CUNY) | From - To (MM/YY – MM/YY) | Jan2000- May2005 |
|---|---|---|---|
| Address: One Bernard Baruch Way | City: New York | State: NY | Zip: 10010 |
| Diploma/Degree obtained, if any | Bachelor of Business Administration | | |

| School Name | Thornton-Donovan School | From - To (MM/YY – MM/YY | Sep1995 - May1999 |
|---|---|---|---|
| Address: 100 Overlook Circle | City: New Rochelle | State: NY | Zip: 10804 |
| Diploma/Degree obtained, if any | High School Diploma | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 11/2017- Present | [redacted] Johnson Rd | Arlington | MA | 02474 |
| 07/2016-11/2017 | [redacted] 1/2 E. Pembroke Rd. | Danbury | CT | 06811 |
| 11/2012-07/2016 | [redacted] Choate rd. | Belmont | MA | 02478 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| | | | | |
|---|---|---|---|---|
| Business Name: Albireo Pharma | | | | From - To (MM/YY – MM/YY): May.2022- Current |
| Business Address: 53 State St., 19th Floor | | City: Boston | State: MA | Zip: 02109 |
| Phone: 617-679-8500 | Title: Sr. Supply Chain Manager | | | Number of Employed Hours: 2000+ |
| Description of Duties: Oversee supply of product to market | | | | |

| | | | | |
|---|---|---|---|---|
| Business Name: QUANTERIX Corp | | | | From - To (MM/YY – MM/YY): Dec. 2015–Apr. 2022 |
| Business Address: 900 Middlesex Tpke. | | City: Billerica | State: MA | Zip: 01821 |
| Phone: 617-301-9400 | Title: Logistics Manager, Distribution Manager – on contract, | | | Number of Employed Hours: 13,000+ |
| Description of Duties: Global Logistics and Distribution management | | | | |

| | | | | |
|---|---|---|---|---|
| Business Name: FedEx Corp. d/b/a TNT USA Inc | | | | From - To (MM/YY – MM/YY): Dec. 2007 – Dec 2015 |
| Business Address: 68 S. Service Rd Ste. 340 | | City: Melville | State: NY | Zip: 11747 |
| Phone: n/a | Title: Account Executive / Operations Supervisor | | | Number of Employed Hours: |
| Description of Duties: Various | | | | |

| | | | | |
|---|---|---|---|---|
| Business Name: | | | | From - To (MM/YY – MM/YY): |
| Business Address: | | City: | State: | Zip: |
| Phone: | Title: | | | Number of Employed Hours: |
| Description of Duties: | | | | |

| | | | | |
|---|---|---|---|---|
| Business Name: | | | | From - To (MM/YY – MM/YY): |
| Business Address: | | City: | State: | Zip: |
| Phone: | Title: | | | Number of Employed Hours: |
| Description of Duties: | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | X |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | X |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | X |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | X |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | X |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | X |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | X |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | X |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | X |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | X |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| | | | | |
| Reason/Charge | | | | |
| | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| | | | | |
| Name of Business/Industry/Entity | | | | |
| | | | | |

**Provide explanation below:**

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Kalin Kantchev, **certify that as the designated representative for**

Albireo Pharma, Inc.,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. ✓ I am at least 21 years of age;
3. ✓ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ✓ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ✓ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ✓ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ✓ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Kalin Kantchev

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

19 Apr 2023

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Kalin Kantchev

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

19 Apr 2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Massachusetts, ss. County of Middlesex

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

19 Apr 2023

**Date**

Subscribed and Sworn to before me this 19th day of April 2023.

**Notary Public Signature**

ABHA ADHIKARI
Notary Public
Commonwealth of Massachusetts
My Commission Expires January 12, 2029

**(Seal)**

# KALIN KANTCHEV, CSCP

[redacted] Johnson Rd. | Arlington, MA 02474 USA [redacted]


Kalin Kantchev

Digitally signed by Kalin Kantchev
DN: cn=Kalin Kantchev, o=Albireo Pharma Inc, ou=Sr. Supply Chain Manager, Technical Operations, email=kalin.kantchev@albireopharma.com, c=US
Reason: I am approving this document
Date: 2022.06.03 15:12:15 -04'00'

Proven track record of gaining "buy-in" in cross-functional setting, analytical, pro-active, focused on continual improvement.

## Education

- MicroMasters in Supply Chain Management, **MIT** — Spring 2019
- Certificate in Supply Chain Management, **Northeastern University** — Fall 2013
- BA in International Business, **Bernard Baruch College (CUNY)** — Spring 2005
  - Magna Cum Laude

## Experience

**Albireo Pharma** — Boston, MA

Sr. Supply Chain Manager — May.2022- Current

- Manage Suppliers
  - Source and Qualify suppliers for services and raw materials (globally)
  - Develop Scorecards and KPIs
- Serialization and Artwork Management
  - Manage the flow of documents and artwork for NPI and New Market Launches
- Facilitate Sales & Operations Planning
  - Drive internal alignment on Forecasting to inform Production Plan

**QUANTERIX Corp** (Biotech, Diagnostics) — Billerica, MA

Supply Chain Manager - on contract — Jan. 2020-Apr. 2022

- Supplier/CMO management
  - Negotiated $12 million ramp-up in spending, qualified suppliers (globally)
  - Created rational segmentation process and developed scorecards and KPIs
- Production Planning
  - Guided unconstrained production plan, leveraged time fences to improve production, VSM mapping for capacity verification and visibility
- Sales & Operations Planning
  - Forecasting improved by 25% in the first two months, Gross Margin improved by 50% and OTIF improved by 20% in three months
- ERP to provide dependable signaling
  - Leveraged reporting and multilevel BOMs to capture demand and drive purchases
  - Improved Master Data to drive process improvements

Distribution Manager - on contract — Jul. 2017 - Jan 2020

- Planed and executed Compliance Program (Export and Import)
  - Created decision trees for CS and Procurement to remain in compliance
- Executed Global Distribution with 50% shipment growth over multiple years
  - Maintained cost per item better than benchmarks, Spearheaded integration with Carriers, 3PLs and improve automation
  - Improved reliability by 90%, while increasing cost only 25% in EU alone

Logistics Manager — Dec. 2015- Jul 2017

- Negotiated pricing and tracked performance, lead improvement efforts
- Managed a team of three in daily outbound order processing

***FedEx Corp.*** (formerly TNT USA INC) — *NY, MA*

*Account Executive / Operations Supervisor* — Dec. 2007 - Dec 2015

- Wrote SOP for all clients, observed specific needs on temperature and handling
  - Following FDA, CBP guidelines and Cold Chain GDP
- Managed a team of eight, plotted trends, analyzed demand to plan workloads and agents

## Skills

- APICS CPIM awarded Sep'2020, CSCP Jul'21 (Certified Supply Chain Professional)
- ERP superuser status. Expert Level in Excel and Microsoft Suite.
- Working knowledge of GxP, FDA Regulatory requirements
- Skilled in using Process Modeling, Value Chain Analysis and Constrained Optimization techniques
- Efficient and skillful negotiator with multi-cultural awareness

**Affiliations:** CSCMP - Council of Supply Chain Management Professionals, IATA/ DOT Dangerous Goods Certification, BIS Export Control

# ALBIREO MA LOCATION EMPLOYEE LIST - 4/19/23

| Employee_FirstName | Employee_LastName |
|---|---|
| Daniel | Aboud |
| Colleen | Alabiso |
| Aimee | Alban |
| Leslie | Askonas |
| Trevor | Baillie |
| Thomas | Barchet |
| Catherine | Barthelemy |
| Judit | Bartis |
| Elliot | Beimel |
| Jennifer | Benenson |
| Michelle | Bice |
| Stefan | Bluemmers |
| Kelsey | Bockus |
| Natasha | Boustani |
| Matthew | Boyd |
| Tara | Bradley |
| Emily | Burgess |
| Martha | Carter |
| Jason | Catherman |
| Anna | Chen |
| Constantine | Chinoporos |
| Anika | Chowdhury |
| Sean | Clark |
| Christine | Clemson |
| Joan | Connolly |
| Ronald | Cooper |
| Frank | Cortazzo |
| Cynthia | Davis |
| Marco | Di Cesare |
| Kenneth | Digioia |
| Brian | DiMarco |
| Colleen | Doyle |
| Michael | Dragone |
| Karen | Evenson |
| Nadine | Ferdenzi |
| Stephanie | Firely |
| David | Franklin |
| Michelle | Freivald |
| Kari | Glenn |
| Juan | Gonzalez |
| Daniela | Gonzalez Tabares |
| Amanda | Goodman |
| Michelle | Graham |

| | |
|---|---|
| John | Grant |
| Melissa | Grossman |
| Tao | Gu |
| Melissa | Guerin |
| Rivka | Gutterman |
| Michelle | Hammerschmidt |
| Alison | Higgins |
| Brian | Hueston |
| Angelyca | Jackson |
| Vinay | Jayakumar |
| Meng | Jia |
| Kalin | Kantchev |
| Matthew | Kent |
| Mary | Keyser |
| Dwight | Kim |
| Matthew | King |
| Donald | Kline |
| Lila | Knisely |
| Benjamin | Kohn |
| Prince | Korah |
| Shweta | Kotecha |
| Emily | Laput |
| Anthony | Loizides |
| Michelle | Long |
| Dennis | Lurlay |
| Sarah | MacMillan |
| Susan | Manganaro |
| Brian | Martinez |
| Jestun | McGuire |
| Aryan | Melville |
| Daniel | Monet |
| Jennifer | Moore |
| Quanhong | Ni |
| Jihyon | Oishi |
| Joanna | Opalinski |
| Joseph | Orsini |
| Lindsey | Paradis |
| Niketkumar | Patel |
| Cassandra | Pauyo |
| Bailey | Peck |
| Changming | Qin |
| Venilde | Reis |
| Jessica | Ruvido |
| Stacy | Sandate |
| Kira | Schott |
| Bhavdeep | Shah |
| Praveen | Sharma |

| | |
|---|---|
| Nanzhu | Shen |
| Sonia | Singh |
| Lucy | Smith |
| Jessica | Snow |
| Debra | Sojka |
| Adam | Soll |
| Carol | Spelman |
| Elizabeth | Spirt |
| Philip | Stein |
| Pamela | Stephenson |
| Stephen | Sullivan |
| Katelyn | Tetrault |
| Carol | Thompson |
| Natasha | Thoren |
| Phuong | Tran |
| Nina | Trapasso |
| Emily | Wallace |
| Mark | Walls |
| Xiaoqiang | Wang |
| Kimberley | Watkins |
| Jordan | Weiss |
| Jeffrey | Werner |
| Deborah | Westwood |
| Jeffrey | Wheeler |
| Michael | Wilkins |
| Amy | Williams |
| Surya | Wiryo |
| Gregory | Wright |
| Qifeng | Yu |

**Albireo NV Customers:**

OPTUM FRONTIER THERAPIES
6425 SANTA MARGARITA ST.
LAS VEGAS, NV 89118

They are only shipping to one location in NV.

# 4D

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

**Non-Refundable $1,000 Fee**

Rev (08/17/2022)

| **Where is the facility located?** | | ☐ Nevada ☒ Out-of-State |
|---|---|---|
| **Type of Application (check applicable box)** | | **Wholesaler Business Type (check applicable box)** |
| ☒ New Wholesaler<br>☐ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH _____ | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: Ascend Laboratories LLC

Physical Address: 339 Jefferson Road, Suite 101

City: Parsippany State: NJ Zip: 07054

Mailing Address (if different from physical address): 339 Jefferson Road

City: Parsippany State: NJ Zip: 07054

Telephone: (201) 476-1977 Website: www.ascendlaboratories.com

Name of Designated Representative (DR): Hindy Schiff

Licensing Company Email: HSchiff@ascendlaboratories.com DR Email: HSchiff@ascendlaboratories.com

| **Entities the Wholesaler will Serve (✓ all applicable)** | **Products to be Handled or Wholesaled (✓ all applicable)** | **Type of Wholesaling (✓ all applicable)** |
|---|---|---|
| ☐ Pharmacies | ☒ Dangerous Drugs | ☒ Manufacturer |
| ☐ Practitioners | ☒ Controlled Substances | ☐ Repacker |
| ☐ Hospitals | ☐ *Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ☒ Wholesalers | ☐ Others: | ☐ Warehouse |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ☐ Others: | | ☐ Others: |

| **Section 2: History of Company** | **Yes** | **No** |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | x |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | x |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | x |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | x |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | x |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

5-23-23

Date

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: No Suppliers sold, dispensed or distributed w/i last year

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

**Section 4: Publicly Traded Corporation**

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: NJ

Parent Company (if any): The PharmaNetwork LLC

Corporation/Organization Name: Ascend Laboratories, LLC

Mailing Address: 339 Jefferson Road

City: Parsippany State: NJ Zip: 07054

Telephone: 201-326-9010 Email: unaik@ascendlaboratories.com

Contact Person Name: Hindy Schiff

**Section 6: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

**Section 7: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | x |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | x | |
| 1. Copy of FDA registration<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** | | ✓ | | |
| • **List of all partners and their percent ownership.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Ascend Laboratories LLC

Facility Name

Hindy Schiff

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

5.23.23

Date

| Board Use Only | Date Received: 7/10/23 | Amount: 1000-CK-17953 ✓ |
|---|---|---|

**Ascend Laboratories LLC Top 4 United States customers of licensee** – names and addresses

Name CVS
Address 1 CVS Drive Woonsocket, RI 02895

Name AmerisourceBergen
Address: 1 WEST FIRST AVENUE, CONSHOHOCKEN, PA 19428

Name McKesson
Address 6555 State Highway 161 Irving, TX, 75039

Name Cardinal
Address: 7000 Cardinal Pl, dublin, oh 43017

## DESCRIPTION OF OPERATIONS

Ascend Laboratories LLC, a Limited Liability Company, is wholly-owned by The PharmaNetwork LLC. Ascend Laboratories LLC is a virtual manufacturer. Ascend Laboratories LLC's product is manufactured by Contract Manufacturers and distributed to wholesalers by a Third-Party Logistics Provider, who is licensed to ship pharmaceutical products into your state. Ascend's product offering includes controlled substance products.

## CONTRACT MANUFACTURERS

Ascend Laboratories LLC uses the following contract manufacturers to produce product:

Alkem Laboratories Ltd
Plot No. 167, Mahatma Gandhi Udyog Nagar, Amaliya, Dabhel
Daman, India 396210
FDA Establishment Number – 3006370524

Alkem Laboratories
Khasra No 1544, 1553, 1558, 1559 Village Thana, Tehsil Nalagarh
Baddi, India 173205
FDA Establishment Number – 3006370533

Patheon Softgels Inc. (Controlled Substance)
4125 Premier Drive
High Point, NC 27265
FDA Establishment Number – 3001451366
DEA License #: RB024892

Crown Laboratories
349 Lafe Cox Drive
Johnson City, TN 37604
FDA Establishment Number – 1019820

## THIRD-PARTY LOGISTICS

For distribution into the commercial supply channels, Ascend Laboratories LLC utilizes the following Third-Party Logistics (3PL) providers to manage the storage and distribution of Ascend Laboratories LLC's product to customers throughout the United States:

| | |
|---|---|
| UPS Supply Chain Solutions, Inc.<br>6200 New Cut Road<br>Fairdale, KY 40118<br>Contact: Andrew Flock; 502.526.7280 | UPS Supply Chain Solutions, LLC<br>1860 Outer Loop<br>Louisville, KY 40219<br>Contact: Marc Via; 502.961.7289 |

Ascend Laboratories LLC, Hours of operation are Monday-Friday 8:00am-6:00pm Eastern Standard Time.

# NEW JERSEY DEPARTMENT OF HEALTH
# CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0748061

**P.O. Box 369, Trenton, New Jersey 08625-0369**

## DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 – "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☒ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

339 JEFFERSON RD, STE 101 PARSIPPANY, NJ 07054-

Reg. No.
5003567

THE PHARMA NETWORK, DBA
ASCEND LABORATORIES, LLC
ATTN: HINDY SCHIFF, REG AFF
339 JEFFERSON ROAD, STE 101
PARSIPPANY, NJ 07054-

**ISSUED PURSUANT TO**
**N.J.S.A. 24:6B**

**EXPIRES: January 31, 2024**

***Establishment Copy***

New Jersey Department of Health
P.O. Box 369, Trenton, New Jersey 08625-0369
Drug and Medical Device Certificate of Registration

Information recorded in the system as of 6/15/2023

**Registration Number:** 5003567 **Registered as:** Manufacturer and Wholesale
**Name:** THE PHARMA NETWORK, DBA
**DBA:** ASCEND LABORATORIES, LLC
**Address:** 339 JEFFERSON RD, STE 101 , PARSIPPANY, NJ 07054
**Original Issue Date:** 11/30/2007 **Expiration Date:** 01/31/2024
**Current Issue Date:** 11/03/2022
**Disciplines:** No

***STATE OF NEW JERSEY***
***DEPARTMENT OF THE TREASURY***
***DIVISION OF REVENUE AND ENTERPRISE SERVICES***
***SHORT FORM STANDING***

***ASCEND LABORATORIES, LLC***
*0600158194*

*I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic Limited Liability Company was registered by this office on January 02, 2003.*

*As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.*

*I further certify that the registered agent and office are:*

*JAMES GIULIANO*
*339 JEFFERSON ROAD*
*SUITE 101*
*PARSIPPANY, NJ 07054*

*IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 24th day of March, 2023*

*Elizabeth Maher Muoio*
*State Treasurer*

*Certificate Number : 6141570070*

*Verify this certificate online at*

*https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp*




## Corporate Information

Ascend Laboratories LLC
339 Jefferson Road Suite 101
Parsippany, NJ 07054
Phone: (201) 476-1977
Website: www.ascendlaboratories.com
HSchiff@ascendlaboratories.com

FEIN: 56-2309125
State of Formation: NJ
Date Incorporated: 01/02/2003

## Ownership Information

Ascend Laboratories LLC, a Limited Liability Company, is 100% owned by The PharmaNetwork LLC.

## Officers

**Amit Ghare, President & CEO**
Business Address: 339 Jefferson Road Parsippany, NJ 07054
Business Phone: (201) 329-9020

**Hindy Schiff, VP Regulatory Affairs and Compliance**
Business Address: 339 Jefferson Road Parsippany, NJ 07054
Business Phone: (201) 326-9010

**John Dillaway, EVP Marketing and Sales**
Business Address: 339 Jefferson Road Parsippany, NJ 07054
Business Phone: (860) 667-7081

DC (index.cfm)

# National Drug Code Directory

Current through June 15, 2023

**You have searched Finished drug products**

**Search Results:** *'67877'*

Back to Search Page () | Search Again ()

CSV | Excel

**Display** 50 **records per page**

**Search for text in the table:**

| Proprietary Name | NDC Package Code | Strength | Dosage Form | Route | Appl. No. | Labeler Name | Product NDC | Nonproprietary Name | Substance Name | Product Type Name | Start Marketing Date | End Marketing Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + Amlodipine and olmesartan Medoxomil | 67877-500-90 | 10 mg/1, 20 mg/1 | TABLET | ORAL | ANDA209042 | Ascend Laboratories, LLC | 67877-500 | Amlodipine and olmesartan Medoxomil | AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL | HUMAN PRESCRIPTION DRUG | 08/14/2017 | N/A |
| + Amlodipine and olmesartan Medoxomil | 67877-499-90 | 5 mg/1, 20 mg/1 | TABLET | ORAL | ANDA209042 | Ascend Laboratories, LLC | 67877-499 | Amlodipine and olmesartan Medoxomil | AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL | HUMAN PRESCRIPTION DRUG | 08/14/2017 | N/A |

| Proprietary Name | NDC Package Code | Strength | Dosage Form | Route | Appl. No. | Labeler Name | Product NDC | Nonproprietary Name | Substance Name | Product Type Name | Start Marketing Date | End Marketing Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + Amlodipine and olmesartan Medoxomil | 67877-501-90 | 5 mg/1, 40 mg/1 | TABLET | ORAL | ANDA209042 | Ascend Laboratories, LLC | 67877-501 | Amlodipine and olmesartan Medoxomil | AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL | HUMAN PRESCRIPTION DRUG | 08/14/2017 | N/A |
| + Amlodipine and olmesartan Medoxomil | 67877-501-30 | 5 mg/1, 40 mg/1 | TABLET | ORAL | ANDA209042 | Ascend Laboratories, LLC | 67877-501 | Amlodipine and olmesartan Medoxomil | AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL | HUMAN PRESCRIPTION DRUG | 08/14/2017 | N/A |
| + Amlodipine and olmesartan Medoxomil | 67877-499-30 | 5 mg/1, 20 mg/1 | TABLET | ORAL | ANDA209042 | Ascend Laboratories, LLC | 67877-499 | Amlodipine and olmesartan Medoxomil | AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL | HUMAN PRESCRIPTION DRUG | 08/14/2017 | N/A |
| + Amlodipine and olmesartan Medoxomil | 67877-500-30 | 10 mg/1, 20 mg/1 | TABLET | ORAL | ANDA209042 | Ascend Laboratories, LLC | 67877-500 | Amlodipine and olmesartan Medoxomil | AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL | HUMAN PRESCRIPTION DRUG | 08/14/2017 | N/A |
| + Amlodipine and olmesartan Medoxomil | 67877-502-30 | 10 mg/1, 40 mg/1 | TABLET | ORAL | ANDA209042 | Ascend Laboratories, LLC | 67877-502 | Amlodipine and olmesartan Medoxomil | AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL | HUMAN PRESCRIPTION DRUG | 08/14/2017 | N/A |
| + Amlodipine and olmesartan Medoxomil | 67877-502-90 | 10 mg/1, 40 mg/1 | TABLET | ORAL | ANDA209042 | Ascend Laboratories, LLC | 67877-502 | Amlodipine and olmesartan Medoxomil | AMLODIPINE BESYLATE; OLMESARTAN MEDOXOMIL | HUMAN PRESCRIPTION DRUG | 08/14/2017 | N/A |
| + Amlodipine Besylate | 67877-197-90 | 2.5 mg/1 | TABLET | ORAL | ANDA078925 | Ascend Laboratories, LLC | 67877-197 | Amlodipine besylate | AMLODIPINE BESYLATE | HUMAN PRESCRIPTION DRUG | 10/20/2010 | N/A |

| Proprietary Name | NDC Package Code | Strength | Dosage Form | Route | Appl. No. | Labeler Name | Product NDC | Nonproprietary Name | Substance Name | Product Type Name | Start Marketing Date | End Marketing Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + Amlodipine Besylate | 67877-199-38 | 10 mg/1 | TABLET | ORAL | ANDA078925 | Ascend Laboratories, LLC | 67877-199 | Amlodipine besylate | AMLODIPINE BESYLATE | HUMAN PRESCRIPTION DRUG | 10/20/2010 | N/A |
| + Amlodipine Besylate | 67877-197-05 | 2.5 mg/1 | TABLET | ORAL | ANDA078925 | Ascend Laboratories, LLC | 67877-197 | Amlodipine besylate | AMLODIPINE BESYLATE | HUMAN PRESCRIPTION DRUG | 10/20/2010 | N/A |
| + Amlodipine Besylate | 67877-197-10 | 2.5 mg/1 | TABLET | ORAL | ANDA078925 | Ascend Laboratories, LLC | 67877-197 | Amlodipine besylate | AMLODIPINE BESYLATE | HUMAN PRESCRIPTION DRUG | 10/20/2010 | N/A |
| + Amlodipine Besylate | 67877-197-38 | 2.5 mg/1 | TABLET | ORAL | ANDA078925 | Ascend Laboratories, LLC | 67877-197 | Amlodipine besylate | AMLODIPINE BESYLATE | HUMAN PRESCRIPTION DRUG | 10/20/2010 | N/A |
| + Amlodipine Besylate | 67877-198-05 | 5 mg/1 | TABLET | ORAL | ANDA078925 | Ascend Laboratories, LLC | 67877-198 | Amlodipine besylate | AMLODIPINE BESYLATE | HUMAN PRESCRIPTION DRUG | 10/20/2010 | N/A |
| + Amlodipine Besylate | 67877-199-05 | 10 mg/1 | TABLET | ORAL | ANDA078925 | Ascend Laboratories, LLC | 67877-199 | Amlodipine besylate | AMLODIPINE BESYLATE | HUMAN PRESCRIPTION DRUG | 10/20/2010 | N/A |
| + Amlodipine Besylate | 67877-198-10 | 5 mg/1 | TABLET | ORAL | ANDA078925 | Ascend Laboratories, LLC | 67877-198 | Amlodipine besylate | AMLODIPINE BESYLATE | HUMAN PRESCRIPTION DRUG | 10/20/2010 | N/A |
| + Amlodipine Besylate | 67877-198-38 | 5 mg/1 | TABLET | ORAL | ANDA078925 | Ascend Laboratories, LLC | 67877-198 | Amlodipine besylate | AMLODIPINE BESYLATE | HUMAN PRESCRIPTION DRUG | 10/20/2010 | N/A |
| + Amlodipine Besylate | 67877-198-90 | 5 mg/1 | TABLET | ORAL | ANDA078925 | Ascend Laboratories, LLC | 67877-198 | Amlodipine besylate | AMLODIPINE BESYLATE | HUMAN PRESCRIPTION DRUG | 10/20/2010 | N/A |

| Proprietary Name | NDC Package Code | Strength | Dosage Form | Route | Appl. No. | Labeler Name | Product NDC | Nonproprietary Name | Substance Name | Product Type Name | Start Marketing Date | End Marketing Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + Amlodipine Besylate | 67877-199-10 | 10 mg/1 | TABLET | ORAL | ANDA078925 | Ascend Laboratories, LLC | 67877-199 | Amlodipine besylate | AMLODIPINE BESYLATE | HUMAN PRESCRIPTION DRUG | 10/20/2010 | N/A |
| + Amlodipine Besylate | 67877-199-90 | 10 mg/1 | TABLET | ORAL | ANDA078925 | Ascend Laboratories, LLC | 67877-199 | Amlodipine besylate | AMLODIPINE BESYLATE | HUMAN PRESCRIPTION DRUG | 10/20/2010 | N/A |
| + Amphetamine Sulfate | 67877-710-01 | 5 mg/1 | TABLET | ORAL | ANDA213720 | Ascend Laboratories, LLC | 67877-710 | Amphetamine Sulfate | AMPHETAMINE SULFATE | HUMAN PRESCRIPTION DRUG | 10/29/2020 | N/A |
| + Amphetamine Sulfate | 67877-711-01 | 10 mg/1 | TABLET | ORAL | ANDA213720 | Ascend Laboratories, LLC | 67877-711 | Amphetamine Sulfate | AMPHETAMINE SULFATE | HUMAN PRESCRIPTION DRUG | 10/29/2020 | N/A |
| + Aripiprazole | 67877-430-01 | 2 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-430 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |
| + Aripiprazole | 67877-430-03 | 2 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-430 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |
| + Aripiprazole | 67877-430-05 | 2 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-430 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |
| + Aripiprazole | 67877-430-32 | 2 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-430 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |
| + Aripiprazole | 67877-430-38 | 2 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-430 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |

| Proprietary Name | NDC Package Code | Strength | Dosage Form | Route | Appl. No. | Labeler Name | Product NDC | Nonproprietary Name | Substance Name | Product Type Name | Start Marketing Date | End Marketing Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + Aripiprazole | 67877-431-01 | 5 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-431 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |
| + Aripiprazole | 67877-431-03 | 5 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-431 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |
| + Aripiprazole | 67877-431-05 | 5 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-431 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |
| + Aripiprazole | 67877-431-32 | 5 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-431 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |
| + Aripiprazole | 67877-431-38 | 5 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-431 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |
| + Aripiprazole | 67877-432-01 | 10 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-432 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |
| + Aripiprazole | 67877-432-03 | 10 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-432 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |
| + Aripiprazole | 67877-432-05 | 10 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-432 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |
| + Aripiprazole | 67877-432-32 | 10 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-432 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |

| Proprietary Name | NDC Package Code | Strength | Dosage Form | Route | Appl. No. | Labeler Name | Product NDC | Nonproprietary Name | Substance Name | Product Type Name | Start Marketing Date | End Marketing Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + Aripiprazole | 67877-432-38 | 10 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-432 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |
| + Aripiprazole | 67877-433-01 | 15 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-433 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |
| + Aripiprazole | 67877-433-03 | 15 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-433 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |
| + Aripiprazole | 67877-433-05 | 15 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-433 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |
| + Aripiprazole | 67877-433-32 | 15 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-433 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |
| + Aripiprazole | 67877-433-38 | 15 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-433 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |
| + Aripiprazole | 67877-434-01 | 20 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-434 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |
| + Aripiprazole | 67877-434-03 | 20 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-434 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |
| + Aripiprazole | 67877-434-05 | 20 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-434 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |

| Proprietary Name | NDC Package Code | Strength | Dosage Form | Route | Appl. No. | Labeler Name | Product NDC | Nonproprietary Name | Substance Name | Product Type Name | Start Marketing Date | End Marketing Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + Aripiprazole | 67877-434-38 | 20 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-434 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |
| + Aripiprazole | 67877-435-01 | 30 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-435 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |
| + Aripiprazole | 67877-435-03 | 30 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-435 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |
| + Aripiprazole | 67877-435-05 | 30 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-435 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |
| + Aripiprazole | 67877-435-38 | 30 mg/1 | TABLET | ORAL | ANDA207105 | Ascend Laboratories, LLC | 67877-435 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG | 02/27/2019 | N/A |

howing 1 to 50 of 915 entries

Previous 1 2 3 4 5 ... 19 Next

**ackground Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)**

rug questions email: **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

ee also: **Drug Registration and Listing Instructions**
**https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)**
**ational Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)**

.S Department of Health and Human Services
ublic Health Service
ood and Drug Administration

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| RU0346088 | 05-31-2024 | $1850 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N,3, 3N,4,5 | DISTRIBUTOR | 04-13-2023 |

U P S SUPPLY CHAIN SOLUTION INC,
1860 OUTER LOOP ROAD
LOUISVILLE, KY 402190000

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

**THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.**

Form DEA-223/511 (9/2016)

**REPORT**

**CHANGES**

**PROMPTLY**

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

**Drug Enforcement Administration**
**P.O. Box 2639**
**Springfield, VA 22152-2639**

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

3PL DEA

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| RU0346088 | 05-31-2024 | $1850 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N,3, 3N,4,5 | DISTRIBUTOR | 04-13-2023 |

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**CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE**
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| RU0346088 | 05-31-2024 | $1850 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N,3, 3N,4,5 | DISTRIBUTOR | 04-13-2023 |

U P S SUPPLY CHAIN SOLUTION INC,
1860 OUTER LOOP ROAD
LOUISVILLE, KY 402190000

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THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)




| Employee Name | Title |
|---|---|
| Amit Ghare | President |
| Laura Kerrigan | Exeutive Administrative Asst |
| John Dillaway | EVP, Sales & Marketing |
| Schuyler Van Winkle | SVP, National Accounts |
| Kylan Ward | Director, National Accounts |
| Lynetter Piers | Director of Sales |
| Kevin Anderson | VP, National Accounts |
| Latoya Smitherman | Assoc Director, Pricing and Cust Service |
| Zaida Gonzalez | Customer Service Mgr |
| Suzanne Messier | Pricing and Contract Analyst |
| Rhonda Browne | Sales Administrator |
| Jordan Melillo | Sales Administrator |
| Urvi Naik | Manager, Regulatory Affairs |
| Hindy Schiiff | VP Of Regulatory Affairs & Compliance |
| Willian Moran | Director of Supply Chain |
| Garima Juneja | Manager, Supply Chain |
| Vishal Joshi | VP of IT |
| Jagannadh Swarna | Sr. Manager, IT |
| Sushant Bhave | IT Manager |
| Scott Bracy | IT Analyst |
| James Giuliano | CFO |
| Timothy Keane | Assoc. Director, Finance |
| Desiree Carpenter | Assoc. Director, Finance |
| Sue Hayes | Senior Rebate Analyst |
| Wanda Agrinsoni | Assoc Director, Gov't Reporting |
| Rolando Morales | Director, Legal & Compliance |
| Amber Livingston | Receptionist |
| Mary Smith | Accounting Director |
| Cindy Lindeberg | HR Manager, Cutomer Returns Manager |
| Donna Bevins | Assoc. Director, Finance |
| Brianna Martin | AR Specialist |
| Chrsitne Aemisegeo | Senior A/R Analyst |

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

**Section 1: Pharmacy/Wholesaler Information**

Name of Pharmacy/Wholesaler Ascend Laboratories LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 339 Jefferson Road, Suite 101

City Parsippany State NJ Zip 07054

Mailing Address (if different from physical address) 339 Jefferson Road

City Parsippany State NJ Zip 07054

Telephone (201) 476-1977 Website www.ascendlaboratories.com

Licensing Company Email HSchiff@ascendlaboratories.com

**Section 2: Personal Information**

First Hindy Middle _____ Last Schiff

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address 339 Jefferson Road Suite 101

City Parsippany State NJ Zip 07054

Telephone [redacted] Email HSchiff@ascendlaboratories.com

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | x |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | x |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | x |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | x |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | N/A | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Kean University | | 09/1971-06/1973 | |
| **Address** | **City** | **State** | **Zip** |
| 1000 Morris Avenue | Union | NJ | 07083 |
| **Diploma/Degree obtained, if any** | | | |
| BA/BS Biology/Chemistry/Med Tech; M.S. in Biochemistry | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| Irvington High School | | 1965-1969 | |
| **Address** | **City** | **State** | **Zip** |
| 1253 Clinton Avenue | Irvington | NJ | 07111 |
| **Diploma/Degree obtained, if any** | | | |
| High School Diploma | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |
| **School Name** | | **From - To (MM/YY – MM/YY** | |
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 1/1997 - Present | [redacted]Jacobs Lane | Scotch Plains | NJ | 07076 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Ascend Laboratories LLC | | | 01/2015 - Present |
| **Business Address** | **City** | **State** | **Zip** |
| 339 Jefferson, Suite 101 | Parsippany | NJ | 07054 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| (201) 476-1977 | VP, Regulatory Affairs and Compliance | 6000+ | |
| **Description of Duties** | | | |
| See Attached Resume | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

Continue on next page if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | x |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | x |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | x |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | x |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | x |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | x |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | x | |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | x |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | x |

ASCEND
Laboratories, LLC

August 9, 2022

To Whom it May Concern:

Ascend Laboratories, LLC is a NJ-based Virtual Manufacturer of pharmaceutical products. As a Virtual Manufacturer, Ascend Laboratories, LLC's product is manufactured by Contract Manufacturers and distributed to wholesalers by a Third-Party Logistics Provider, who is licensed to distribute pharmaceuticals into your state.

The Maine Board of Pharmacy website indicates that Ascend Laboratories, LLC was "Denied" licensure. While the application was denied, this was not a result of non-compliance or disciplinary action by Ascend.

In late 2020, Ascend Laboratories applied for a Manufacturer license through the Maine Board of Pharmacy. Ascend complied with all of Maine's requests for supporting documentation and submitted the required application fee. In December 2020, Maine notified Ascend that they do not license Virtual Manufacturer entities. As a result, the Maine Board of Pharmacy website indicates that Ascend was "Denied" licensure. Ascend is currently working with the state of Maine to possibly resolve this matter and remove the denial from the state website.

I hope this narrative provides the clarity needed to continue the review of Ascend's application.

Sincerely,



Urvi Naik
Senior Manager, Regulatory Affairs

I, Hindy Schiff, **certify that as the designated representative for**

Ascend Laboratories LLC,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. _____ I am at least 21 years of age;
3. _____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. _____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. _____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. _____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. _____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Hindy Schiff

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6-7-23

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Hindy Schiff
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1-24-23
Date

---

**Please have this section completed in the presence of a Notary Public.**

State of New Jersey, ss. County of Morris

I, Laura Kerrigan, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

1-24-23
**Date**

Subscribed and Sworn to before me this 24th day of JANUARY.

**Notary Public Signature**

(Seal)

LAURA M. KERRIGAN
NOTARY PUBLIC OF NEW JERSEY
MY COMMISSION EXPIRES JANUARY 22, 2026

Hindy Schiff
[redacted]acobs Lane
Scotch Plains, New Jersey 07076
Mobile ([redacted]

## SUMMARY

Senior level Regulatory Affairs and Compliance professional with over 20 years of successful strategic and operational leadership in registration of generic drugs (ANDAs), 505(b) (2) drugs (NDAs), sNDAs, medical device and sterile products (combination drugs) and implementation of corporate compliance.

Demanding and skillful hands-on leader who empowers associates and colleagues by highlighting their respective ability while operating as a cohesive team to support the organization. Thorough project planner accustomed to a fast pace and multiple projects.

Successful record of accomplishments with the Food and Drug Administration at the District level and FDA Washington. Knowledgeable with hands on experience in different aspects of the pharmaceutical industry including Regulatory Affairs, Quality Management, Production and Technical Development departments.

Excellent working knowledge of Regulatory Guidance's, cGMP, Quality Systems, and current industry practices. Strong interpersonal and communication skills with the ability to interact with all levels of management and subordinates.

## PROFESSIONAL EXPERIENCE

**Ascend Laboratories**
**Parsippany, New Jersey**
**2017- Present**
**Vice President Regulatory Affairs and Compliance**
**US Agent**
Executive Regulatory Affairs and Compliance professional for all of the company Regulatory and Compliance activity. FDA US Agent for Alkem Laboratories.
Accomplishments:

- FDA US Agent for Alkem Laboratories, India. Built a strong and trusted relationship with the FDA regulatory staff.
- Provide extensive experience in strategy development, communicating with FDA and deficiency management.
- Provide US leadership for mature products in various therapeutic areas; ensure maintenance of mature product portfolio.
- Training and development of direct report and cross-functional teams on FDA regulations and guidance(s).
- Compliance Officer maintaining the company in compliance with cGMPs for distribution (federal and state).

**2015 - 2017**
**Senior Director Regulatory Affairs**
**US Agent**
Senior individual in charge of Regulatory Affairs for the domestic and international business of Ascend Laboratories and Alkem Laboratories, India.

**Ivax/CorePharma**
**Middlesex, New Jersey**
**2010 – August 2012**
**Senior Director Regulatory Affairs**
Responsible for all Regulatory Affairs activities for the company. Member of the Management and Quality Council teams.
Accomplishments:

- Senior individual responsible for managing all regulatory activities involving unapproved, approved and marketed drug products.
- Member of the due diligences team for product acquisition.
- Proven track record of guiding filings through FDA approval process.
- Interpretation of relevant federal regulations to develop Company regulatory policy.
- Provides regulatory input to product development teams, including detailed regulatory strategies regarding ANDA and NDA filings.
- Oversees and responsible for compilation and submission of all regulatory documents to FDA. Submissions include labeling changes, annual reports, adverse event reporting and all FDA communications.

- Represents Company to FDA and other health authorities on regulatory issues involving project issues.
- Supports marketed products with regulatory review of product labeling and advertising materials. Coordinates with other departments to achieve regulatory project goals.
- Regulatory review and oversight for all advertising and promotional materials of pre and post approved products.
- Work closely with Sales and Marketing in critically reviewing all advertising and promotional materials.
- Oversees entire company labeling program for pre and post approved products including preparing and filing all supplements.
- Direct interaction with FDA's OPDP for company.
- Provided regulatory input and strategies for new acquired combination drug (sterile product/medical device). Worked closely with FDA to get product back into the marketplace.
- Review current policies and practices issued by Federal regulatory agencies and update Company management as needed.
- Oversees Pharmacovigilance for the company.
- Reports directly to the CEO of the company.
- Controls and determines department budget.

**Eagle Pharmaceuticals**
**Woodcliff Lake, New Jersey** **2007 – 2009**
**Vice President Regulatory Affairs**

Executive in charge of Regulatory Affairs for the domestic and international business of Eagle Pharmaceuticals. Eagle was a start-up, specialty, virtual pharmaceutical company utilizing specialized technologies to develop novel dosage forms, product presentations, and difficult to develop and manufacture generic solid dosage form and parenteral products.

Accomplishments:

- Lead and manage Regulatory function, advise on regulatory strategies for generic drugs and 505(b)(2) program, handle all Regulatory Authority communications, meeting strategies and submissions, provide regulatory intelligence and guidance, develop strong working relationship with partners and contractors.
- Oversaw the domestic and international Regulatory Affairs for the company and its partners.
- Received approval to file for ANDA and 505(b) (2) applications and continued to work closely with the agency to get applications approved for marketing.
- Scheduled and attended meetings with FDA on numerous products and issues.
- Close working relationship with various Divisions at FDA.
- Worked on various dosage forms including sterile products, semi-solids, solids and liquids.

**G&W Laboratories**
**South Plainfield, New Jersey** **1995-2007**
**1997-2007**
**Vice President Regulatory Affairs and Quality Assurance**

Executive in charge of Regulatory Affairs and Quality Assurance for the company. Member of the Executive Committee for G&W Laboratories.

Accomplishments:

- Responsible for and directs all corporate Regulatory Affairs, Quality Assurance and Compliance. Oversees all new ANDA submissions, amendments, supplements and correspondence with FDA

and numerous government agencies. Conducts all pre-approval, post approval and on-site cGMP FDA inspections.

- Interacts and advises all areas of the company with a focus on Operations and Scientific Affairs while ensuring compliance to cGMPs.
- Filed and received approval for numerous ANDAs, including Biowaiver and Paragraph IV filings.
- Primary FDA contact both at the District and Center level. Organizes and attends on-site Agency meeting and telephone conference when necessary.
- Supports marketed products with regulatory review of product labeling and advertising materials. Coordinates with other departments to achieve regulatory project goals.
- Regulatory review and oversight for all advertising and promotional materials of pre and post approved products.
- Oversees entire company labeling program for pre and post approved products including preparing and filing all supplements. Direct interaction with FDA's OPDP for company.
- Reports directly to the President and CEO of the company.
- Maintains and oversees a multi-million dollar budget
- Directs and oversees new Quality Systems and Quality by Design.

**1995-1997**

**Director Regulatory Affairs and Quality Assurance**

Responsible for all Regulatory Affairs and Quality departments and functions in the generic drug business of G&W Laboratories.

Accomplishments:

- Established a quality standard that ensures compliance with cGMPs including but not limited to documentation control, internal and vendor audits, raw material review, finished product review, quarantine cage deviation/investigations, training, complaints, change control, labeling, validations, and SOPs.
- Directed and implemented company remediation initiative as a result of FDA cGMP inspection.

**Chase-Banner Pharmacaps Pharmaceuticals**
**Newark, New Jersey** **1992-1995**
**1994-1995**
**Senior Manager Regulatory Affairs**

Accomplishments:

- Assured Company Compliance with cGMPs, internal Quality Standards and Regulatory Authority regulations.
- Involved/directed activities between the company and FDA. Ensured the proper submissions of regulatory documents, interpreting government specifications for NDA's and ANDA's, determining the use of appropriate data and reports in regulatory submissions with adherence to content and format requirements.
- Established and directed activities related to the regulatory and scientific functions for the company, Regulatory Affairs and Quality Assurance.
- Directed and guided company's labeling program, Auditing program, and Validation and Vendor Certification efforts.

**1992-1994**

**Senior Regulatory Affairs Associate/Technical Specialist**

Accomplishments:

- Developed and put into practice corporate policies for Regulatory Affairs, Quality and Manufacturing for the corporation.
- Coordinated the development of labeling for new products and labeling revisions for existing products.
- Assured corporate compliance with cGMP's, audits and training of personnel.
- Involved in submission of regulatory documents, interpreting government specifications for NDA's and ANDA's, determining the use of appropriate data and reports in regulatory submissions with adherence to content and format requirements.
- Assisted and involved in process/facility validation procedures for the corporation.
- Responsible for reviewing and sign-off on manufacturing master batch records and label approval requests.
- Organize product complaint investigations and responses.

## EDUCATION

BA/BS Kean University, Union, New Jersey, Biology/Chemistry/Medical Technology
Masters Biochemistry

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

## PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 806969

Application/License No. _____

ASCEND LABORATORIES LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 339 JEFFERSON ROAD PARSIPPANY, NJ 07054 (Address of Applicant/Principal), as PRINCIPAL, and HUDSON INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of DELAWARE (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1035 GREENWOOD BLVD STE 265 LAKE MARY, FL 32746 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on JANUARY 13, 2022 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 10TH day of JANUARY, 2023.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

Surety Company's Representative

ERIC FAUERBACH, Attorney-in-fact
print name

Hudson Insurance Company CORPORATE SEAL 1918 DELAWARE B503

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

LAURA M. KERRIGAN
NOTARY PUBLIC OF NEW JERSEY
MY COMMISSION EXPIRES JANUARY 22, 2026

Countersigned by:

Not Needed
Nevada Resident Agent

HUDSON INSURANCE GROUP

Bond Number: 806969

# POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That HUDSON INSURANCE COMPANY, a corporation of the State of Delaware, with offices at 100 William Street, New York, New York, 10038, has made, constituted and appointed, and by these presents, does make, constitute and appoint

Eric Fauerbach

**of the State of** South Carolina

its true and lawful Attorney(s)-in-Fact, at New York, New York, each of them alone to have full power to act without the other or others, to make, execute and deliver on its behalf, as Surety, bonds and undertakings given for any and all purposes, also to execute and deliver on its behalf as aforesaid renewals, extensions, agreements, waivers, consents or stipulations relating to such bonds or undertakings provided, however, that no single bond or undertaking shall obligate said Company for any portion of the penal sum thereof in excess of the sum of

Twenty Five Thousand And 00/100 Dollars ($25,000.00)

Such bonds and undertakings when duly executed by said Attorney(s)-in-Fact, shall be binding upon said Company as fully and to the same extent as if signed by the President of said Company under its corporate seal attested by its Secretary.

In Witness Whereof, HUDSON INSURANCE COMPANY has caused these presents to be of its Senior Vice President thereunto duly
d, on this 2nd day of June, 20 22 at New York, New York.
: seal)

**HUDSON INSURANCE COMPANY**

Attest.....
**Dina Daskalakis No. 01MU6067553**
Corporate Secretary

By.....
**Michael P. Cifone**
Senior Vice President

STATE OF NEW YORK
COUNTY OF NEW YORK. SS.

On the 2nd day of June, 20 22 before me personally came Michael P. Cifone to me known, who being by me duly sworn did depose and say that he is a Senior Vice President of **HUDSON INSURANCE COMPANY**, the corporation described herein and which executed the above instrument, that he knows the seal of said Corporation, that the seal affixed to said instrument is such corporate seal, that it was so affixed by order of the Board of Directors of said Corporation, and that he signed his name thereto by like order.

(Notarial Seal)

.....
**ANN M. MURPHY**
Notary Public, State of New York
No. 01MU6067553
Qualified in Nassau County
Commission Expires December 10, 2025

## CERTIFICATION

STATE OF NEW YORK
COUNTY OF NEW YORK SS.

The undersigned **Dina Daskalakis** hereby certifies:

That the original resolution, of which the following is a true and correct copy, was duly adopted by unanimous written consent of the Board of Directors of Hudson Insurance Company dated July 27th, 2007, and has not since been revoked, amended or modified:

"RESOLVED, that the President, the Executive Vice Presidents, the Senior Vice Presidents and the Vice Presidents shall have the authority and discretion, to appoint such agent or agents, or attorney or attorneys-in-fact, for the purpose of carrying on this Company's surety business, and to empower such agent or agents, or attorney or attorneys-in-fact, to execute and deliver, under this Company's seal or otherwise, bonds obligations, and recognizances, whether made by this Company as surety thereon or otherwise, indemnity contracts, contracts and certificates, and any and all other contracts and undertakings made in the course of this Company's surety business, and renewals, extensions, agreements, waivers, consents or stipulations regarding undertakings so made; and

FURTHER RESOVLED, that the signature of any such Officer of the Company and the Company's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seal when so used whether heretofore or hereafter, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed."

THAT the above and foregoing is a full, true and correct copy of Power of Attorney issued by said Company, and of the whole of the original and that the said Power of Attorney is still in full force and effect and has not been revoked, and furthermore that the Resolution of the Board of Directors, set forth in the said Power of Attorney is now in force.

Witness the hand of the undersigned and the seal of said Corporation this 10th day of January, 2023.
(Corporate seal)

By.....
**Dina Daskalakis,** Corporate Secretary

# 4E

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

**Non-Refundable $1,000 Fee**

Rev (08/17/2022)

| **Where is the facility located?** | | ☐ Nevada ■ Out-of-State |
|---|---|---|
| **Type of Application (check applicable box)** | | **Wholesaler Business Type (check applicable box)** |
| ■ New Wholesaler<br>☐ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH _____ | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: Brainlab Inc

Physical Address: 5 Westbrook Corporate Center Suite 1000

City: Westchester State: IL Zip: 60154

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 708-409-1343 Website: https://www.brainlab.com/

Name of Designated Representative (DR): Sean Clark

Licensing Company Email: sean.clark@brainlab.com DR Email: sean.clark@brainlab.com

| **Entities the Wholesaler will Serve (✓ all applicable)** | **Products to be Handled or Wholesaled (✓ all applicable)** | **Type of Wholesaling (✓ all applicable)** |
|---|---|---|
| ☐ Pharmacies | ☐ Dangerous Drugs | ☐ Manufacturer |
| ☐ Practitioners | ☐ Controlled Substances | ☐ Repacker |
| ■ Hospitals | ■ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ☐ Wholesalers | ☐ Others: | ☐ Warehouse |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ☐ Others: | | ■ Others: sales |

| **Section 2: History of Company** | **Yes** | **No** |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✓ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | ✓ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | ✓ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✓ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # _____. **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

Date

Name: Brainlab AG

Address: Olof-Palme-Straße 9 City: Munich State: Germa Zip: 81829

**Name:**

**Address:** **City:** **State:** **Zip:**

Name:

Address: City: State: Zip:

**Name:**

**Address:** **City:** **State:** **Zip:**

**Section 4: Publicly Traded Corporation**

State of Incorporation:

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: Delaware

Parent Company (if any): Brainlab AG

Corporation/Organization Name: Brainlab Inc.

Mailing Address: 5 Westbrook Corporate Center Suite 1000

City: Westchester State: IL Zip: 60154

Telephone: 708-409-1343 Email: paul.neil@brainlab.com

Contact Person Name: Paul Neil

**Section 6: Partnership**

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

**Section 7: Sole Owner**

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

| Section A: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | ✓ |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | ✓ | |
| 1. Copy of FDA registration<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |

| Section B: Provide the following documents with your application based on your business type. Required documents are indicated by an "✓" on the right. | Primary Owner | Non-Primary Owners | Partner Only | Non-Profit Only |
|---|---|---|---|---|
| • **List of all Officers and Directors.** | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** | | ✓ | | |
| • **List of all partners and their percent ownership.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). | ✓ | ✓ | ✓ | ✓ |
| **Only Complete Below If Your Company is NOT Accredited by NABP and/or Has a License/Certificate in Section A** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Brainlab, Inc.

Facility Name

Sean M. Clark

Print Name of Authorized Person Submitting Application

Sean M. Clark

Original signature of Authorized Person (copies or stamps not accepted)

20 JUN 23

Date

| Board Use Only | Date Received: 7/3/23 | Amount: 1000-CK-082763 |
|---|---|---|

BRAINLAB

**Brainlab, Inc.**
5 Westbrook Corporate Center · Suite 1000
Westchester, IL 60154 · USA
phone: +1 708 409 1343
fax: +1 708 409 1619

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

July 13, 2023

Dear Sir or Madam,

Brainlab Inc. has not had any administrative action by any licensing board in any state whether it is a disciplinary action or citation either pending or completed.

Sincerely,

Sean M. Clark
President

FDA

FDA Home[3] Medical Devices[4] Databases[5]

## Establishment Registration & Device Listing

New Search

Back To Search Results

**Establishment:**
BRAINLAB, INC.
5 Westbrook Corporate Ctr Ste 1000
WESTCHESTER, IL 60154
**Registration Number:** 2248788
**FEI Number*:** 3000206463
**Status:** Active
**Initial Distributor/Importer:** Yes
*Note Firm May Have Additional Establishment Types. Please Review Listings For Further Information.
**Date Of Registration Status:** 2023

Verified 7.3.23 SB

**Owner/Operator:**
BrainLAB, Inc.[6]
5 Westbrook Corporate Center, Ste. 1000
Westchester, IL US 60154
**Owner/Operator Number:** 9027196[7]

**Official Correspondent:**
Paul Neil
5 Westbrook Corporate Center
Ste. 1000
Westchester, IL 60154
**Phone:** 708-4861971

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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Page Last Updated: 06/19/2023

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

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BRAINLAB

Brainlab, Inc.
5 Westbrook Corporate Center · Suite 1000
Westchester, IL 60154 · USA
phone: +1 708 409 1343
fax: +1 708 409 1619

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

**June 20, 2023**

To whom it may concern,

Enclosed please fined the Wholesaler Application for Brainlab, Inc., a medical device sales and service organization.

With respect to Section 9 of the Wholesaler Application, Brainlab submits the following:

1. Directors: Stefan Vilsmeier
   Officers: President: Sean M. Clark
   CEO: Stefan Vilsmeier
   Compliance Officer: Paul Neil
2. N/A – top four shareholders
3. Sole corporate shareholder is Brainlab AG, a German company
4. N/A – partner list
5. Certificate of Good Standing is enclosed.
6. Designated representative Form is enclosed.
7. Personal History Record Application – N/A; Given that there are no Individual shareholders, we are not submitting the Personal History Record Application.
8. N/A – DEA certificate
9. N/A – SEC 10K or 8K
10. Reserved; we do not agree to provide a full listing of all employees; Brainlab employees roughly 350 people across the United States. Additionally we do not find a list of lenders germane to the application.
11. N/A – Neither the Delaware (state of incorporation) Board of Pharmacy nor the Illinois (home state) Illinois Department of Financial and Professional Regulation required license for selling and servicing medical devices.
12. Medical Devices, Equipment and Gases Administrator form is enclosed.
13. Certificate of insurance is enclosed.
14. Bond
15. Copy of FDA registration
16. Registration Fee

Please contact me with any questions.

Sincerely,
Meg Ramer
Senior Corporate Counsel

# Delaware

The First State



I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "BRAINLAB, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SIXTH DAY OF DECEMBER, A.D. 2022.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "BRAINLAB, INC." WAS INCORPORATED ON THE TWENTY-FIRST DAY OF OCTOBER, A.D. 1998.

Jeffrey W. Bullock, Secretary of State

2956429 8300

SR# 20224192926

Authentication: 205024559

Date: 12-06-22

You may verify this certificate online at corp.delaware.gov/authver.shtml

HBL
NOT REQUIRED



## Illinois Compiled Statutes



**Information maintained by the Legislative Reference Bureau**
Updating the database of the Illinois Compiled Statutes (ILCS) is an ongoing process. Recent laws may not yet be included in the ILCS database, but they are found on this site as Public Acts soon after they become law. For information concerning the relationship between statutes and Public Acts, refer to the Guide.

Because the statute database is maintained primarily for legislative drafting purposes, statutory changes are sometimes included in the statute database before they take effect. If the source note at the end of a Section of the statutes includes a Public Act that has not yet taken effect, the version of the law that is currently in effect may have already been removed from the database and you should refer to that Public Act to see the changes made to the current law.

## PROFESSIONS, OCCUPATIONS, AND BUSINESS OPERATIONS
## (225 ILCS 120/) Wholesale Drug Distribution Licensing Act.

(225 ILCS 120/1) (from Ch. 111, par. 8301-1)
(Section scheduled to be repealed on January 1, 2028)
Sec. 1. Short title. This Act may be cited as the Wholesale Drug Distribution Licensing Act.
(Source: P.A. 87-594.)

(225 ILCS 120/3)
Sec. 3. (Repealed).
(Source: P.A. 95-689, eff. 10-29-07. Repealed by P.A. 102-879, eff. 1-1-23.)

(225 ILCS 120/5) (from Ch. 111, par. 8301-5)
(Section scheduled to be repealed on January 1, 2028)
Sec. 5. Scope. This Act applies to any person, partnership, corporation, or business firm engaging in the wholesale distribution of human prescription drugs within this State.
(Source: P.A. 87-594.)

(225 ILCS 120/10) (from Ch. 111, par. 8301-10)
(Section scheduled to be repealed on January 1, 2028)
Sec. 10. Purpose. The purpose of this Act is to implement the Federal Prescription Drug Marketing Act of 1987 (PDMA), U.S. Pub. L. 100-293, 102 Stat. 95, codified at U.S.C. Sec. 321 et seq.; and particularly PDMA requirements that no person or entity may engage in the wholesale distribution of human prescription drugs in any state unless the person or entity is licensed by that state in accordance with federally prescribed minimum standards, terms, and conditions as set forth in guidelines issued by United States Food and Drug Administration (FDA) regulations.
(Source: P.A. 87-594.)

(225 ILCS 120/15) (from Ch. 111, par. 8301-15)
(Section scheduled to be repealed on January 1, 2028)
Sec. 15. Definitions. As used in this Act:
"Address of record" means the designated address recorded by the Department in the applicant's application file or licensee's

license file maintained by the Department's licensure maintenance unit.

"Authentication" means the affirmative verification, before any wholesale distribution of a prescription drug occurs, that each transaction listed on the pedigree has occurred.

"Authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between a wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in Section 1504 of the Internal Revenue Code, complies with the following:

(1) The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing the ongoing relationship; and

(2) The wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis.

"Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

"Blood component" means that part of blood separated by physical or mechanical means.

"Board" means the State Board of Pharmacy of the Department of Professional Regulation.

"Chain pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of the drugs to a group of chain or mail order pharmacies that have the same common ownership and control. Notwithstanding any other provision of this Act, a chain pharmacy warehouse shall be considered part of the normal distribution channel.

"Co-licensed partner or product" means an instance where one or more parties have the right to engage in the manufacturing or marketing of a prescription drug, consistent with the FDA's implementation of the Prescription Drug Marketing Act.

"Department" means the Department of Financial and Professional Regulation.

"Drop shipment" means the sale of a prescription drug to a wholesale distributor by the manufacturer of the prescription drug or that manufacturer's co-licensed product partner, that manufacturer's third-party logistics provider, or that manufacturer's exclusive distributor or by an authorized distributor of record that purchased the product directly from the manufacturer or one of these entities whereby the wholesale distributor or chain pharmacy warehouse takes title but not physical possession of such prescription drug and the wholesale distributor invoices the pharmacy, chain pharmacy warehouse, or other person authorized by law to dispense or administer such drug to a patient and the pharmacy, chain pharmacy warehouse, or other authorized person receives delivery of the prescription drug directly from the manufacturer, that manufacturer's third-party logistics provider, or that manufacturer's exclusive distributor or from an authorized distributor of record that purchased the product directly from the manufacturer or one of these entities.

"Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

"Email address of record" means the designated email address recorded by the Department in the applicant's application file or the licensee's license file, as maintained by the Department's licensure maintenance unit.

"Facility" means a facility of a wholesale distributor where prescription drugs are stored, handled, repackaged, or offered for sale, or a facility of a third-party logistics provider where prescription drugs are stored or handled.

"FDA" means the United States Food and Drug Administration.

"Manufacturer" means a person licensed or approved by the FDA to engage in the manufacture of drugs or devices, consistent with the definition of "manufacturer" set forth in the FDA's regulations and guidances implementing the Prescription Drug Marketing Act. "Manufacturer" does not include anyone who is engaged in the packaging, repackaging, or labeling of drugs only to the extent permitted under the Illinois Drug Reuse Opportunity Program Act.

"Manufacturer's exclusive distributor" means anyone who contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug. A manufacturer's exclusive distributor must be licensed as a wholesale distributor under this Act and, in order to be considered part of the normal distribution channel, must also be an authorized distributor of record.

"Normal distribution channel" means a chain of custody for a prescription drug that goes, directly or by drop shipment, from (i) a manufacturer of the prescription drug, (ii) that manufacturer to that manufacturer's co-licensed partner, (iii) that manufacturer to that manufacturer's third-party logistics provider, or (iv) that manufacturer to that manufacturer's exclusive distributor to:

(1) a pharmacy or to other designated persons authorized by law to dispense or administer the drug to a patient;

(2) a wholesale distributor to a pharmacy or other designated persons authorized by law to dispense or administer the drug to a patient;

(3) a wholesale distributor to a chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer the drug to a patient;

(4) a chain pharmacy warehouse to the chain pharmacy warehouse's intracompany pharmacy or other designated persons authorized by law to dispense or administer the drug to the patient;

(5) an authorized distributor of record to one other authorized distributor of record to an office-based health care practitioner authorized by law to dispense or administer the drug to the patient; or

(6) an authorized distributor to a pharmacy or other persons licensed to dispense or administer the drug.

"Pedigree" means a document or electronic file containing information that records each wholesale distribution of any given prescription drug from the point of origin to the final wholesale distribution point of any given prescription drug.

"Person" means and includes a natural person, partnership, association, corporation, or any other legal business entity.

"Pharmacy distributor" means any pharmacy licensed in this State or hospital pharmacy that is engaged in the delivery or distribution of prescription drugs either to any other pharmacy licensed in this State or to any other person or entity including, but not limited to, a wholesale drug distributor engaged in the delivery or distribution of prescription drugs who is involved in the actual, constructive, or attempted transfer of a drug in this State to other than the ultimate

consumer except as otherwise provided for by law.

"Prescription drug" means any human drug, including any biological product (except for blood and blood components intended for transfusion or biological products that are also medical devices), required by federal law or regulation to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to Section 503 of the Federal Food, Drug and Cosmetic Act.

"Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug, excluding that completed by the pharmacist responsible for dispensing the product to a patient.

"Secretary" means the Secretary of the Department of Financial and Professional Regulation.

"Suspicious order" includes, but is not limited to, an order of a controlled substance of unusual size, an order of a controlled substance deviating substantially from a normal pattern, and orders of controlled substances of unusual frequency as defined by 21 USC 802.

"Third-party logistics provider" means anyone who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition.

"Wholesale distribution" means the distribution of prescription drugs to persons other than a consumer or patient, but does not include any of the following:

(1) Intracompany sales of prescription drugs, meaning (i) any transaction or transfer between any division, subsidiary, parent, or affiliated or related company under the common ownership and control of a corporate entity or (ii) any transaction or transfer between co-licensees of a co-licensed product.

(2) The sale, purchase, distribution, trade, or transfer of a prescription drug or offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons.

(3) The distribution of prescription drug samples by manufacturers' representatives.

(4) Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with federal regulation.

(5) The sale of minimal quantities of prescription drugs by licensed pharmacies to licensed practitioners for office use or other licensed pharmacies.

(6) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription.

(7) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy or pharmacies from or with another pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets.

(8) The sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record when the manufacturer has stated in writing to the receiving authorized distributor of record that the manufacturer is unable to supply the prescription drug and the supplying authorized distributor of record states in writing that the prescription drug being supplied had until that time been exclusively in the normal distribution channel.

(9) The delivery of or the offer to deliver a

prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs when the common carrier does not store, warehouse, or take legal ownership of the prescription drug.

(10) The sale or transfer from a retail pharmacy, mail order pharmacy, or chain pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer, the originating wholesale distributor, or a third party returns processor.

(11) The donation of drugs to the extent permitted under the Illinois Drug Reuse Opportunity Program Act.

"Wholesale drug distributor" means anyone engaged in the wholesale distribution of prescription drugs into, out of, or within the State, including without limitation manufacturers; repackers; own label distributors; jobbers; private label distributors; brokers; warehouses, including manufacturers' and distributors' warehouses; manufacturer's exclusive distributors; and authorized distributors of record; drug wholesalers or distributors; independent wholesale drug traders; specialty wholesale distributors; and retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution. In order to be considered part of the normal distribution channel, a wholesale distributor must also be an authorized distributor of record.
(Source: P.A. 101-420, eff. 8-16-19; 102-389, eff. 1-1-22; 102-879, eff. 1-1-23.)

(225 ILCS 120/15.5)
(Section scheduled to be repealed on January 1, 2028)

Sec. 15.5. Address of record; email address of record. All applicants and licensees shall:

(1) provide a valid address and email address to the Department, which shall serve as the address of record and email address of record, respectively, at the time of application for licensure or renewal of a license; and

(2) inform the Department of any change of address of record or email address of record within 14 days after such change either through the Department's website or by contacting the Department's licensure maintenance unit.
(Source: P.A. 102-879, eff. 1-1-23.)

(225 ILCS 120/20) (from Ch. 111, par. 8301-20)
(Section scheduled to be repealed on January 1, 2028)

Sec. 20. Prohibited drug purchases or receipt. It shall be unlawful for any person or entity located in this State to knowingly receive any prescription drug from any source other than a person or entity required by the laws of this State to be licensed to ship into, out of, or within this State. A person or entity licensed under the laws of this State shall include, but is not limited to, a wholesale distributor, manufacturer, third-party logistics provider, pharmacy distributor, or pharmacy. Any person violating this Section shall, upon conviction, be adjudged guilty of a Class C misdemeanor. A second violation shall constitute a Class 4 felony.
(Source: P.A. 101-420, eff. 8-16-19.)

(225 ILCS 120/21)
(Section scheduled to be repealed on January 1, 2028)

Sec. 21. Reports to Department. Each licensee that is required to report suspicious orders under 21 USC 832 shall also submit such suspicions order reports to the Department.
(Source: P.A. 102-879, eff. 1-1-23.)

(225 ILCS 120/24)

Sec. 24. (Repealed).

(Source: P.A. 95-689, eff. 10-29-07. Repealed by P.A. 98-692, eff. 7-1-14.)

(225 ILCS 120/25) (from Ch. 111, par. 8301-25)

(Section scheduled to be repealed on January 1, 2028)

Sec. 25. Wholesale drug distributor licensing requirements.

(a) Every resident wholesale distributor who engages in the wholesale distribution of prescription drugs must be licensed by the Department, and every non-resident wholesale distributor must be licensed in this State if it ships prescription drugs into this State, in accordance with this Act, before engaging in wholesale distributions of wholesale prescription drugs.

(b) The Department shall require without limitation all of the following information from each applicant for licensure under this Act:

(1) The name, full business address, and telephone number of the licensee.

(2) All trade or business names used by the licensee.

(3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of prescription drugs.

(4) The type of ownership or operation, such as a partnership, corporation, or sole proprietorship.

(5) The name of the owner or operator of the wholesale distributor, including:

(A) if a natural person, the name of the natural person;

(B) if a partnership, the name of each partner and the name of the partnership;

(C) if a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and

(D) if a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

(6) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs.

(7) The name of the designated representative for the wholesale distributor, together with the personal information statement and fingerprints, as required under subsection (c) of this Section.

(8) Minimum liability insurance and other insurance as defined by rule.

(9) Any additional information required by the Department.

(c) Each wholesale distributor must designate an individual representative who shall serve as the contact person for the Department. This representative must provide the Department with all of the following information:

(1) Information concerning whether the person has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or State law regulating the possession, control, or distribution of prescription drugs or criminal violations, together with details concerning any such event.

(2) A description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund which manufactured, administered, prescribed,

distributed, or stored pharmaceutical products and any lawsuits in which such businesses were named as a party.

(3) A description of any misdemeanor or felony criminal offense of which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendere. If the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of that criminal offense, the applicant must, within 15 days after the disposition of the appeal, submit to the Department a copy of the final written order of disposition.

(4) The designated representative of an applicant for licensure as a wholesale drug distributor shall have his or her fingerprints submitted to the Illinois State Police in an electronic format that complies with the form and manner for requesting and furnishing criminal history record information as prescribed by the Illinois State Police. These fingerprints shall be checked against the Illinois State Police and Federal Bureau of Investigation criminal history record databases now and hereafter filed. The Illinois State Police shall charge applicants a fee for conducting the criminal history records check, which shall be deposited into the State Police Services Fund and shall not exceed the actual cost of the records check. The Illinois State Police shall furnish, pursuant to positive identification, records of Illinois convictions to the Department. The Department may require applicants to pay a separate fingerprinting fee, either to the Department or to a vendor. The Department, in its discretion, may allow an applicant who does not have reasonable access to a designated vendor to provide his or her fingerprints in an alternative manner. The Department may adopt any rules necessary to implement this Section.

The designated representative of a licensee shall receive and complete continuing training in applicable federal and State laws governing the wholesale distribution of prescription drugs.

(d) The Department may not issue a wholesale distributor license to an applicant, unless the Department first:

(1) ensures that a physical inspection of the facility satisfactory to the Department has occurred at the address provided by the applicant, as required under item (1) of subsection (b) of this Section; and

(2) determines that the designated representative meets each of the following qualifications:

(A) He or she is at least 21 years of age.

(B) He or she has been employed full-time for at least 3 years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and recordkeeping relating to, prescription drugs.

(C) He or she is employed by the applicant full time in a managerial level position.

(D) He or she is actively involved in and aware of the actual daily operation of the wholesale distributor.

(E) He or she is physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized, including without limitation sick leave and vacation leave.

(F) He or she is serving in the capacity of a

designated representative for only one applicant at a time, except where more than one licensed wholesale distributor is co-located in the same facility and such wholesale distributors are members of an affiliated group, as defined in Section 1504 of the Internal Revenue Code.

(e) If a wholesale distributor distributes prescription drugs from more than one facility, the wholesale distributor shall obtain a license for each facility.

(f) The information provided under this Section may not be disclosed to any person or entity other than the Department or another government entity in need of such information for licensing or monitoring purposes.

(Source: P.A. 102-538, eff. 8-20-21.)

(225 ILCS 120/25.5)

(Section scheduled to be repealed on January 1, 2028)

Sec. 25.5. Third-party logistics providers.

(a) Each resident third-party logistics provider must be licensed by the Department, and every non-resident third-party logistics provider must be licensed in this State, in accordance with this Act, prior to shipping a prescription drug into this State.

(b) The Department shall require, without limitation, all of the following information from each applicant for licensure under this Act:

(1) The name, full business address, and telephone number of the licensee.

(2) All trade or business names used by the licensee.

(3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of prescription drugs.

(4) The type of ownership or operation, such as a partnership, corporation, or sole proprietorship.

(5) The name of the owner or operator of the third-party logistics provider, including:

(A) if a natural person, the name of the natural person;

(B) if a partnership, the name of each partner and the name of the partnership;

(C) if a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and

(D) if a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

(6) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs.

(7) The name of the designated representative for the third-party logistics provider, together with the personal information statement and fingerprints, as required under subsection (c) of this Section.

(8) Minimum liability insurance and other insurance as defined by rule.

(9) Any additional information required by the Department.

(c) Each third-party logistics provider must designate an individual representative who shall serve as the contact person for the Department. This representative must provide the Department with all of the following information:

(1) Information concerning whether the person has

been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or State law regulating the possession, control, or distribution of prescription drugs or criminal violations, together with details concerning any such event.

(2) A description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, that manufactured, administered, prescribed, distributed, or stored pharmaceutical products and any lawsuits in which such businesses were named as a party.

(3) A description of any misdemeanor or felony criminal offense of which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendere. If the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of that criminal offense, the applicant must, within 15 days after the disposition of the appeal, submit to the Department a copy of the final written order of disposition.

(4) The designated representative of an applicant for licensure as a third-party logistics provider shall have his or her fingerprints submitted to the Department of State Police in an electronic format that complies with the form and manner for requesting and furnishing criminal history record information as prescribed by the Department of State Police. These fingerprints shall be checked against the Department of State Police and Federal Bureau of Investigation criminal history record databases now and hereafter filed. The Department of State Police shall charge applicants a fee for conducting the criminal history records check, which shall be deposited into the State Police Services Fund and shall not exceed the actual cost of the records check. The Department of State Police shall furnish, pursuant to positive identification, records of Illinois convictions to the Department. The Department may require applicants to pay a separate fingerprinting fee, either to the Department or to a vendor. The Department, in its discretion, may allow an applicant who does not have reasonable access to a designated vendor to provide his or her fingerprints in an alternative manner. The Department may adopt any rules necessary to implement this paragraph (4).

(d) A third-party logistics provider shall not operate from a place of residence.

(e) A third-party logistics provider facility shall be located apart and separate from any retail pharmacy licensed by the Department.

(f) The Department may not issue a third-party logistics provider license to an applicant, unless the Department first:

(1) ensures that a physical inspection of the facility satisfactory to the Department has occurred at the address provided by the applicant, as required under item (1) of subsection (b) of this Section; such inspection is not required if the resident state of the third-party logistics provider facility does not license third-party logistics providers or if the resident state does not inspect third-party logistics providers. If the resident state does not inspect third-party logistics providers, a Verified Accredited Wholesale Distributors Accreditation or other inspection approved by the Department meets this requirement; and

(2) determines that the designated representative

meets each of the following qualifications:

(A) He or she is at least 21 years of age.

(B) He or she is employed by the applicant full time in a managerial level position.

(C) He or she is actively involved in and aware of the actual daily operation of third-party logistics provider.

(g) A third-party logistics provider shall publicly display all licenses and have the most recent state and federal inspection reports readily available.

(Source: P.A. 101-420, eff. 8-16-19.)

(225 ILCS 120/26)

(Section scheduled to be repealed on January 1, 2028)

Sec. 26. Unlicensed practice; violation; civil penalty.

(a) Any person who practices, offers to practice, attempts to practice, or holds oneself out to practice as a wholesale drug distributor, pharmacy distributor, or third-party logistics provider without being licensed to ship into, out of, or within the State under this Act shall, in addition to any other penalty provided by law, pay a civil penalty to the Department in an amount not to exceed $10,000 for each offense as determined by the Department. The civil penalty shall be assessed by the Department after a hearing is held in accordance with the provisions set forth in this Act regarding the provision of a hearing for the discipline of a licensee.

(b) The Department has the authority and power to investigate any and all unlicensed activity.

(c) The civil penalty shall be paid within 60 days after the effective date of the order imposing the civil penalty. The order shall constitute a judgment and may be filed and execution had thereon in the same manner as any judgment from any court of record.

(Source: P.A. 101-420, eff. 8-16-19.)

(225 ILCS 120/27)

(Section scheduled to be repealed on January 1, 2028)

Sec. 27. Social security number, individual taxpayer identification number, or unique identifying number on license application. In addition to any other information required to be contained in the application, every application for an original license under this Act shall include the applicant's social security number, individual taxpayer identification number, or other unique identifying number deemed appropriate by the Department, which shall be retained in the agency's records pertaining to the license. As soon as practical, the Department shall assign a customer's identification number to each applicant for a license.

Every application for a renewal or restored license shall require the applicant's customer identification number.

(Source: P.A. 102-879, eff. 1-1-23.)

(225 ILCS 120/30) (from Ch. 111, par. 8301-30)

(Section scheduled to be repealed on January 1, 2028)

Sec. 30. License applications; renewal procedures. An application for an original license or renewal shall be made to the Department in writing or electronically on forms prescribed by the Department and shall be accompanied by the required fee, which shall not be refundable. Any such application shall require such information as in the judgment of the Department will enable the Board and Department to pass on the qualifications of the applicant for a license. If the application for renewal with the required fee is not received by the Department before the expiration date, the existing license

shall lapse and become null and void. Failure to renew before the expiration date is cause for a late payment penalty, discipline, or both.
(Source: P.A. 101-420, eff. 8-16-19; 102-879, eff. 1-1-23.)

(225 ILCS 120/31)
(Section scheduled to be repealed on January 1, 2028)
Sec. 31. Expiration of license; renewal.

(a) The expiration date and renewal period for each license issued under this Act shall be set by rule.

(b) Any licensee who shall engage in the practice for which the license was issued while the license is expired or on inactive status shall be considered to be practicing without a license which shall be grounds for discipline under this Act.

(c) A wholesale drug distributor or third-party logistics provider whose license has been expired for one year or more may not have its license restored but must apply for a new license and meet all requirements for licensure. Any wholesale drug distributor or third-party logistics provider whose license has been expired for less than one year may apply for restoration of its license and shall have its license restored.

(d) Anyone operating on an expired license is engaged in unlawful practice and subject to discipline under this Act.
(Source: P.A. 102-879, eff. 1-1-23.)

(225 ILCS 120/35) (from Ch. 111, par. 8301-35)
(Section scheduled to be repealed on January 1, 2028)
Sec. 35. Fees; Illinois State Pharmacy Disciplinary Fund.

(a) The Department shall provide by rule for a schedule of fees for the administration and enforcement of this Act, including but not limited to original licensure, renewal, and restoration. The fees shall be nonrefundable.

(b) All fees collected under this Act shall be deposited into the Illinois State Pharmacy Disciplinary Fund and shall be appropriated to the Department for the ordinary and contingent expenses of the Department in the administration of this Act. Moneys in the Fund may be transferred to the Professions Indirect Cost Fund as authorized by Section 2105-300 of the Department of Financial and Professional Regulation Law (20 ILCS 2105/2105-300).

The moneys deposited into the Illinois State Pharmacy Disciplinary Fund shall be invested to earn interest which shall accrue to the Fund.

(c) Any person who delivers a check or other payment to the Department that is returned to the Department unpaid by the financial institution upon which it is drawn shall pay to the Department, in addition to the amount already owed to the Department, a fine of $50. The fines imposed by this Section are in addition to any other discipline provided under this Act for unlicensed practice or practice on a nonrenewed license. The Department shall notify the person that payment of fees and fines shall be paid to the Department by certified check or money order within 30 calendar days of the notification. If, after the expiration of 30 days from the date of the notification, the person has failed to submit the necessary remittance, the Department shall automatically terminate the license or certificate or deny the application, without hearing. If, after termination or denial, the person seeks a license or certificate, he or she shall apply to the Department for restoration or issuance of the license or certificate and pay all fees and fines due to the Department. The Department may establish a fee for the processing of an application for restoration of a license or certificate to pay all expenses of processing this application. The Secretary may waive the fines

due under this Section in individual cases where the Secretary finds that the fines would be unreasonable or unnecessarily burdensome.

(d) (Blank).

(e) A manufacturer of controlled substances, wholesale distributor of controlled substances, or third-party logistics provider that is licensed under this Act and owned and operated by the State is exempt from licensure, registration, renewal, and other fees required under this Act. Nothing in this subsection (e) shall be construed to prohibit the Department from imposing any fine or other penalty allowed under this Act.
(Source: P.A. 101-420, eff. 8-16-19; 102-879, eff. 1-1-23.)

(225 ILCS 120/40) (from Ch. 111, par. 8301-40)
(Section scheduled to be repealed on January 1, 2028)

Sec. 40. Rules and regulations. The Department shall make any rules and regulations, not inconsistent with law, as may be necessary to carry out the purposes and enforce the provisions of this Act. All rules and regulations promulgated under this Section shall conform to wholesale drug distributor licensing guidelines formally adopted by the FDA at 21 C.F.R. Part 205. In case of conflict between any rule or regulation adopted by the Department and any FDA wholesale drug distributor or third-party logistics provider guideline, the FDA guideline shall control.
(Source: P.A. 101-420, eff. 8-16-19; 102-879, eff. 1-1-23.)

(225 ILCS 120/45)
Sec. 45. (Repealed).
(Source: P.A. 87-594. Repealed by P.A. 95-689, eff. 10-29-07.)

(225 ILCS 120/50) (from Ch. 111, par. 8301-50)
(Section scheduled to be repealed on January 1, 2028)

Sec. 50. Inspection powers; access to records.

(a) Any pharmacy investigator authorized by the Department has the right of entry for inspection of premises purporting or appearing to be used by a wholesale drug distributor in this State, including the business premises of a person licensed pursuant to this Act. This right of entry shall permit the authorized pharmacy investigator unfettered access to the entire business premises. Any attempt to hinder an authorized pharmacy investigator from inspecting the business premises and documenting the inspection shall be a violation of this Act. The duly authorized investigators shall be required to show appropriate identification before being given access to a wholesale drug distributor's premises and delivery vehicles.

(b) With the exception of the most recent 12 months of records that must be kept on the premises where the drugs are stored, wholesale drug distributors may keep records regarding purchase and sales transactions electronically at a central location apart from the principal office of the wholesale drug distributor or the location at which the drugs were stored and from which they were shipped, provided that the records shall be made readily available for inspection within 2 working days of a request by the Department. The records may be kept in any form permissible under federal law applicable to prescription drugs record keeping.

(c) (Blank).
(Source: P.A. 102-879, eff. 1-1-23.)

(225 ILCS 120/55) (from Ch. 111, par. 8301-55)
(Section scheduled to be repealed on January 1, 2028)

Sec. 55. Discipline; grounds.

(a) The Department may refuse to issue, restore, or renew,

or may revoke, suspend, place on probation, reprimand or take other disciplinary or non-disciplinary action as the Department may deem appropriate, including imposing fines not to exceed $10,000 for each violation, with regard to any applicant or licensee or any officer, director, manager, or shareholder who owns 5% or more interest in the business that holds the license for any one or a combination of the following reasons:

(1) Violation of this Act or of the rules adopted under this Act.

(2) Aiding or assisting another person in violating any provision of this Act or the rules adopted under this Act.

(3) Failing, within 60 days, to provide information in response to a written requirement made by the Department.

(4) Engaging in dishonorable, unethical, or unprofessional conduct of a character likely to deceive, defraud, or harm the public. This includes violations of "good faith" as defined by the Illinois Controlled Substances Act and applies to all prescription drugs.

(5) Discipline by another U.S. jurisdiction or foreign nation, if at least one of the grounds for the discipline is the same or substantially equivalent to those set forth in this Act.

(6) Selling or engaging in the sale of drug samples provided at no cost by drug manufacturers.

(7) Conviction by plea of guilty or nolo contendere, finding of guilt, jury verdict, or entry of judgment or by sentencing of any crime, including, but not limited to, convictions, preceding sentences of supervision, conditional discharge, or first offender probation, under the laws of any jurisdiction of the United States that is (i) a felony or (ii) a misdemeanor, an essential element of which is dishonesty or that is directly related to the practice of this profession.

(8) Habitual or excessive use or addiction to alcohol, narcotics, stimulants, or any other chemical agent or drug by the designated representative, as provided for in item (7) of subsection (b) of Section 25 of this Act, any officer, or director that results in the inability to function with reasonable judgment, skill, or safety.

(9) Material misstatement in furnishing information to the Department.

(10) A finding by the Department that the licensee, after having his or her license placed on probationary status, has violated the terms of probation.

(11) Fraud or misrepresentation in applying for, or procuring, a license under this Act or in connection with applying for renewal of a license under this Act.

(12) Willfully making or filing false records or reports.

(13) A finding of a substantial discrepancy in a Department audit of a prescription drug, including a controlled substance as that term is defined in this Act or in the Illinois Controlled Substances Act.

(14) Falsifying a pedigree or selling, distributing, transferring, manufacturing, repackaging, handling, or holding a counterfeit prescription drug intended for human use.

(15) Interfering with a Department investigation.

(16) Failing to adequately secure controlled substances or other prescription drugs from diversion.

(17) Acquiring or distributing prescription drugs not obtained from a source licensed by the Department.

(18) Failing to properly store drugs.

(19) Failing to maintain the licensed premises with proper storage and security controls.

(b) The Department may refuse to issue or may suspend the license or registration of any person who fails to file a return, or to pay the tax, penalty or interest shown in a filed return, or to pay any final assessment of tax, penalty or interest, as required by any tax Act administered by the Illinois Department of Revenue, until the time the requirements of the tax Act are satisfied.

(c) The Department shall revoke the license or certificate of registration issued under this Act or any prior Act of this State of any person who has been convicted a second time of committing any felony under the Illinois Controlled Substances Act or the Methamphetamine Control and Community Protection Act or who has been convicted a second time of committing a Class 1 felony under Sections 8A-3 and 8A-6 of the Illinois Public Aid Code. A person whose license or certificate of registration issued under this Act or any prior Act of this State is revoked under this subsection (c) shall be prohibited from engaging in the practice of pharmacy in this State.

(Source: P.A. 97-804, eff. 1-1-13; 97-813, eff. 7-13-12; 98-463, eff. 8-16-13.)

(225 ILCS 120/56)

(Section scheduled to be repealed on January 1, 2028)

Sec. 56. Restrictions on transactions.

(a) A licensee shall receive prescription drug returns or exchanges from a pharmacy or other persons authorized to administer or dispense drugs or a chain pharmacy warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse. Returns of expired, damaged, recalled, or otherwise non-saleable pharmaceutical products shall be distributed by the receiving wholesale distributor only to either the original manufacturer or a third party returns processor. Returns or exchanges of prescription drugs, saleable or otherwise, including any redistribution by a receiving wholesaler, shall not be subject to the pedigree requirements of Section 57 of this Act, so long as they are exempt from the pedigree requirement of the FDA's currently applicable Prescription Drug Marketing Act guidance. Both licensees under this Act and pharmacies or other persons authorized to administer or dispense drugs shall be accountable for administering their returns process and ensuring that the aspects of this operation are secure and do not permit the entry of adulterated and counterfeit product.

(b) A manufacturer or wholesale distributor licensed under this Act may furnish prescription drugs only to a person licensed by the appropriate state licensing authorities. Before furnishing prescription drugs to a person not known to the manufacturer or wholesale distributor, the manufacturer or wholesale distributor must affirmatively verify that the person is legally authorized to receive the prescription drugs by contacting the appropriate state licensing authorities.

(c) Prescription drugs furnished by a manufacturer or wholesale distributor licensed under this Act may be delivered only to the premises listed on the license, provided that the manufacturer or wholesale distributor may furnish prescription drugs to an authorized person or agent of that person at the premises of the manufacturer or wholesale distributor if:

(1) the identity and authorization of the recipient is properly established; and

(2) this method of receipt is employed only to meet

the immediate needs of a particular patient of the authorized person.

(d) Prescription drugs may be furnished to a hospital pharmacy receiving area, provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug received. Any discrepancy between the receipt and the type and quantity of the prescription drug actually received shall be reported to the delivering manufacturer or wholesale distributor by the next business day after the delivery to the pharmacy receiving area.

(e) A manufacturer or wholesale distributor licensed under this Act may not accept payment for, or allow the use of, a person or entity's credit to establish an account for the purchase of prescription drugs from any person other than the owner of record, the chief executive officer, or the chief financial officer listed on the license of a person or entity legally authorized to receive the prescription drugs. Any account established for the purchase of prescription drugs must bear the name of the licensee. This subsection (e) shall not be construed to prohibit a pharmacy or chain pharmacy warehouse from receiving prescription drugs if payment for the prescription drugs is processed through the pharmacy's or chain pharmacy warehouse's contractual drug manufacturer or wholesale distributor.

(Source: P.A. 95-689, eff. 10-29-07.)

(225 ILCS 120/57)

(Section scheduled to be repealed on January 1, 2028)

Sec. 57. Pedigree.

(a) Each person who is engaged in the wholesale distribution of prescription drugs, including repackagers, but excluding the original manufacturer of the finished form of the prescription drug, that leave or have ever left the normal distribution channel shall, before each wholesale distribution of the drug, provide a pedigree to the person who receives the drug. A retail pharmacy, mail order pharmacy, or chain pharmacy warehouse must comply with the requirements of this Section only if the pharmacy or chain pharmacy warehouse engages in the wholesale distribution of prescription drugs. On or before July 1, 2009, the Department shall determine a targeted implementation date for electronic track and trace pedigree technology. This targeted implementation date shall not be sooner than July 1, 2010. Beginning on the date established by the Department, pedigrees may be implemented through an approved and readily available system that electronically tracks and traces the wholesale distribution of each prescription drug starting with the sale by the manufacturer through acquisition and sale by any wholesale distributor and until final sale to a pharmacy or other authorized person administering or dispensing the prescription drug. This electronic tracking system shall be deemed to be readily available only upon there being available a standardized system originating with the manufacturers and capable of being used on a wide scale across the entire pharmaceutical chain, including manufacturers, wholesale distributors, third-party logistics providers, and pharmacies. Consideration must also be given to the large-scale implementation of this technology across the supply chain and the technology must be proven to have no negative impact on the safety and efficacy of the pharmaceutical product.

(b) Each person who is engaged in the wholesale distribution of a prescription drug who is provided a pedigree for a prescription drug and attempts to further distribute that prescription drug, including repackagers, but excluding the

original manufacturer of the finished form of the prescription drug, must affirmatively verify before any distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

(c) The pedigree must include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer or the manufacturer's third-party logistics provider, co-licensed product partner, or exclusive distributor through acquisition and sale by any wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the drug. This necessary chain of distribution information shall include, without limitation all of the following:

(1) The name, address, telephone number and, if available, the e-mail address of each owner of the prescription drug and each wholesale distributor of the prescription drug.

(2) The name and address of each location from which the product was shipped, if different from the owner's.

(3) Transaction dates.

(4) Certification that each recipient has authenticated the pedigree.

(d) The pedigree must also include without limitation all of the following information concerning the prescription drug:

(1) The name and national drug code number of the prescription drug.

(2) The dosage form and strength of the prescription drug.

(3) The size of the container.

(4) The number of containers.

(5) The lot number of the prescription drug.

(6) The name of the manufacturer of the finished dosage form.

(e) Each pedigree or electronic file shall be maintained by the purchaser and the wholesale distributor for at least 3 years from the date of sale or transfer and made available for inspection or use within 5 business days upon a request of the Department.

(Source: P.A. 101-420, eff. 8-16-19; 102-879, eff. 1-1-23.)

(225 ILCS 120/58)

(Section scheduled to be repealed on January 1, 2028)

Sec. 58. Prohibited acts. It is unlawful for a person to perform or cause the performance of or aid and abet any of the following acts:

(1) Failure to obtain a license in accordance with this Act or operating without a valid license when a license is required by this Act.

(2) If the requirements of subsection (a) of Section 56 of this Act are applicable and are not met, the purchasing or otherwise receiving of a prescription drug from a pharmacy.

(3) If licensure is required pursuant to subsection (b) of Section 56 of this Act, the sale, distribution, or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the prescription drug to receive the prescription drug.

(4) Failure to deliver prescription drugs to specified premises, as required by subsection (c) of Section 56 of this Act.

(5) Accepting payment or credit for the sale of prescription drugs in violation of subsection (e) of Section 56 of this Act.

(6) Failure to maintain or provide pedigrees as required by this Act.

(7) Failure to obtain, pass, or authenticate a pedigree as required by this Act.

(8) Providing the Department or any federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the provisions of this Act.

(9) Obtaining or attempting to obtain a prescription drug by fraud, deceit, or misrepresentation or engaging in misrepresentation or fraud in the distribution of a prescription drug.

(10) The manufacture, repacking, sale, transfer, delivery, holding, or offering for sale of any prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or that has otherwise been rendered unfit for distribution, except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved under federal law by the FDA.

(11) The adulteration, misbranding, or counterfeiting of any prescription drug, except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved under federal law by the FDA.

(12) The receipt of any prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit and the delivery or proffered delivery of such drug for pay or otherwise.

(13) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of a prescription drug or the commission of any other act with respect to a prescription drug that results in the prescription drug being misbranded. The acts prohibited in this Section do not include the obtaining or the attempt to obtain a prescription drug for the sole purpose of testing the prescription drug for authenticity performed by a prescription drug manufacturer or the agent of a prescription drug manufacturer.

(Source: P.A. 95-689, eff. 10-29-07.)

(225 ILCS 120/59)

(Section scheduled to be repealed on January 1, 2028)

Sec. 59. Injunctive action; cease and desist order.

(a) If any person violates the provisions of this Act, the Secretary, in the name of the People of the State of Illinois, through the Attorney General or the State's Attorney of the county where the violation is alleged to have occurred, may petition for an order enjoining the violation or for an order enforcing compliance with this Act. Upon the filing of a verified petition, the court with appropriate jurisdiction may issue a temporary restraining order, without notice or bond, and may preliminarily and permanently enjoin the violation. If it is established that the person has violated or is violating the injunction, then the court may punish the offender for contempt of court. Proceedings under this Section are in addition to, and not in lieu of, all other remedies and penalties provided by this Act.

(b) Whenever, in the opinion of the Department, a person violates any provision of this Act, the Department may issue a rule to show cause why an order to cease and desist shall not be entered against that person. The rule shall clearly set forth the grounds relied upon by the Department and shall allow a

person at least 7 days after the date of the rule to file an answer satisfactory to the Department. Failure to answer to the satisfaction of the Department shall cause an order to cease and desist to be issued.
(Source: P.A. 97-804, eff. 1-1-13.)

(225 ILCS 120/60) (from Ch. 111, par. 8301-60)
(Section scheduled to be repealed on January 1, 2028)

Sec. 60. Wholesaler licensing; complaints. The Department may refuse to issue a license to establish a new licensed wholesale drug distributorship, if an owner of the wholesale drug distributorship applying for a license was an owner of a wholesale drug distributorship that had its license revoked, unless the owner presents sufficient evidence indicating rehabilitation. Once a complaint has been filed by the Department against a wholesale drug distributorship the Department may refuse to issue a license to establish a new licensed wholesale drug distributorship, until such time as the Department issues a decision on the complaint if an owner of the new wholesale drug distributorship was also an owner of a wholesale drug distributorship against which the complaint was filed. Neither an application for change of ownership nor for a change of location for any such wholesale drug distributorship shall be acted on by the Department until such time as the Department issues a decision on the complaint. In the event that the wholesale drug distributorship against which the complaint has been filed ceases to be licensed by the Department, for any reason, before the Department's decision on the complaint and an owner or that wholesale drug distributorship applies for a license to establish a new wholesale drug distributorship, the Department shall conduct a hearing on the complaint earlier filed, regardless of whether that wholesale drug distributorship is presently licensed by the Department. If the conduct for which the complaint was originally filed would have been sufficient to result in a revocation of a license to operate a licensed wholesale drug distributorship, then the conduct shall constitute sufficient grounds for denial of an application for a license.
(Source: P.A. 87-594.)

(225 ILCS 120/65) (from Ch. 111, par. 8301-65)
(Section scheduled to be repealed on January 1, 2028)

Sec. 65. Pending disciplinary proceeding. The Department shall render no final administrative decision relative to any application for a license or certificate of registration under this Act if the applicant for the license or certificate of registration is the subject of a pending disciplinary proceeding under this Act or another Act administered by the Department. For purposes of this Section "applicant" means an individual or sole proprietor, or an individual who is an officer, director, or owner of a 5% or more beneficial interest in the applicant.
(Source: P.A. 87-594.)

(225 ILCS 120/70) (from Ch. 111, par. 8301-70)
(Section scheduled to be repealed on January 1, 2028)

Sec. 70. Immediate suspension of license or registration; hearing. The Secretary may, upon receipt of a written communication from the Secretary of Human Services or the Director of Public Health that continuation of practice of a person licensed or registered under this Act constitutes an immediate danger to the public, immediately suspend the license or registration of that person without a hearing. In instances in which the Secretary immediately suspends a license or registration under this Section, a hearing upon the person's

license must be convened by the Board within 15 days after the suspension and completed without appreciable delay. The hearing shall be held to determine whether to recommend to the Secretary that the person's license be revoked, suspended, placed on probationary status, or reinstated, or that the person be subject to other disciplinary action. In the hearing, the written communication and any other evidence submitted with the communication may be introduced as evidence against the person. The person or his or her counsel shall have the opportunity to discredit or impeach such evidence and submit rebuttal evidence.
(Source: P.A. 102-879, eff. 1-1-23.)

(225 ILCS 120/75) (from Ch. 111, par. 8301-75)
(Section scheduled to be repealed on January 1, 2028)

Sec. 75. Automatic suspension. The determination by a circuit court that a licensee is subject to involuntary admission or judicial admission as provided in the Mental Health and Developmental Disabilities Code operates as an automatic suspension. The suspension shall end only upon (i) a finding by a court that the patient is no longer subject to involuntary admission or judicial admission and the issuance of an order so finding and discharging the patient and (ii) the recommendation of the Board to the Secretary that the licensee be allowed to resume his or her practice.
(Source: P.A. 102-879, eff. 1-1-23.)

(225 ILCS 120/80) (from Ch. 111, par. 8301-80)
(Section scheduled to be repealed on January 1, 2028)

Sec. 80. Violations of Act.

(a) If any person violates the provisions of this Act, the Secretary may, in the name of the People of the State of Illinois through the Attorney General of the State of Illinois or the State's Attorney of any county in which the action is brought, petition for an order enjoining the violation or for an order enforcing compliance with this Act. Upon the filing of a verified petition in the court, the court may issue a temporary restraining order, without notice or bond, and may preliminarily and permanently enjoin the violation. If it is established that the person has violated or is violating the injunction, the Court may punish the offender for contempt of court. Proceedings under this Section shall be in addition to, and not in lieu of, all other remedies and penalties provided by this Act.

(b) Whoever knowingly conducts business as a wholesale drug distributor or third-party logistics provider in this State without being appropriately licensed under this Act shall be guilty of a Class A misdemeanor for a first violation and for each subsequent conviction shall be guilty of a Class 4 felony.

(c) Whenever in the opinion of the Department any person not licensed in good standing under this Act violates any provision of this Act, the Department may issue a rule to show cause why an order to cease and desist should not be entered against him. The rule shall clearly set forth the grounds relied upon by the Department and shall provide a period of 7 days from the date of the rule to file an answer to the satisfaction of the Department. Failure to answer to the satisfaction of the Department shall cause an order to cease and desist to be issued immediately.
(Source: P.A. 101-420, eff. 8-16-19; 102-879, eff. 1-1-23.)

(225 ILCS 120/85) (from Ch. 111, par. 8301-85)
(Section scheduled to be repealed on January 1, 2028)

Sec. 85. Investigations; notice of disciplinary hearing. The Department may investigate the actions of any applicant or of any person or persons holding or claiming to hold a license or

registration. Before suspending, revoking, placing on probationary status, or taking any other disciplinary action as the Department may deem proper with regard to any license or certificate, at least 30 days before the date set for the hearing, the Department shall (i) notify the accused in writing of any charges made and the time and place for a hearing of the charges before the Board, (ii) direct him or her to file a written answer to the charges with the Board under oath within 20 days after the service of the notice, and (iii) inform the accused that if he or she fails to file an answer default will be taken against him or her and his or her license or certificate may be suspended, revoked, placed on probationary status, or have other disciplinary action, including limiting the scope, nature or extent of business, as provided for in this Act. The written notice may be served by personal delivery, email to the respondent's email address of record, or mail to the respondent's address of record. At the time and place fixed in the notice, the Board shall proceed to hear the charges and the parties or their counsel shall be accorded ample opportunity to present any statements, testimony, evidence and argument that may be pertinent to the charges or to their defense. The hearing may be continued from time to time. In case the accused person, after receiving notice, fails to file an answer, his or her license or certificate may in the discretion of the Secretary, having received first the recommendation of the Board, be suspended, revoked, placed on probationary status, or the Secretary may take whatever disciplinary action as he or she may deem proper as provided in this Act, including limiting the scope, nature, or extent of the person's practice, without a hearing, if the act or acts charged constitute sufficient grounds for such action under this Act.
(Source: P.A. 102-879, eff. 1-1-23.)

(225 ILCS 120/90) (from Ch. 111, par. 8301-90)
(Section scheduled to be repealed on January 1, 2028)

Sec. 90. Record of proceedings. The Department, at its expense, shall preserve a record of all proceedings at the formal hearing of any case involving the refusal to issue or renew a license or discipline of a licensee. The notice of hearing, complaint, and all other documents in the nature of pleadings and written motions filed in the proceedings, the transcript of testimony, the report of the Board or hearing officer, and orders of the Department shall be the record of the proceeding.
(Source: P.A. 87-594.)

(225 ILCS 120/95) (from Ch. 111, par. 8301-95)
(Section scheduled to be repealed on January 1, 2028)

Sec. 95. Order requiring attendance of witnesses and production of evidence. Any circuit court may, upon application of the Department or its designee or of the applicant or licensee against whom proceedings of this Act are pending, enter an order requiring the attendance of witnesses and their testimony and the production of documents, papers, files, books and records in connection with any hearing or investigation. The court may compel obedience to its order by proceedings for contempt.
(Source: P.A. 87-594.)

(225 ILCS 120/100) (from Ch. 111, par. 8301-100)
(Section scheduled to be repealed on January 1, 2028)

Sec. 100. Subpoena power; administration of oaths. The Department shall have power to subpoena and bring before it any person in this State and to take testimony, either orally or by

(225 ILCS 120/145) (from Ch. 111, par. 8301-145)
(Section scheduled to be repealed on January 1, 2028)

Sec. 145. Restoration of certificate. At any time after suspension or revocation of any certificate, the Department may restore it to the accused person upon the written recommendation of the Board.
(Source: P.A. 87-594.)

(225 ILCS 120/150) (from Ch. 111, par. 8301-150)
(Section scheduled to be repealed on January 1, 2028)

Sec. 150. Surrender of license or registration. Upon the revocation or suspension of any license or registration, the holder shall immediately surrender the license or registration to the Department and if the licensee fails to do so, the Department shall have the right to seize the license or certificate.
(Source: P.A. 87-594.)

(225 ILCS 120/155) (from Ch. 111, par. 8301-155)
(Section scheduled to be repealed on January 1, 2028)

Sec. 155. Temporary suspension of license; hearing. The Secretary may temporarily suspend licensure as a wholesale drug distributor or third-party logistics provider, without a hearing, simultaneously with the institution of proceedings for a hearing provided for in Section 85 of this Act, if the Secretary finds that evidence in his or her possession indicates that a continuation in business would constitute an imminent danger to the public. In the event that the Secretary temporarily suspends a license or certificate without a hearing, a hearing by the Department must be held within 10 days after the suspension has occurred and be concluded without appreciable delay.
(Source: P.A. 101-420, eff. 8-16-19; 102-879, eff. 1-1-23.)

(225 ILCS 120/160) (from Ch. 111, par. 8301-160)
(Section scheduled to be repealed on January 1, 2028)

Sec. 160. Administrative Review Law; venue. All final administrative decisions of the Department are subject to judicial review under the Administrative Review Law and its rules. The term "administrative decision" is defined as in Section 3-101 of the Code of Civil Procedure.

Proceedings for judicial review shall be commenced in the circuit court of the county in which the party applying for review resides; but if the party is not a resident of this State, the venue shall be in Sangamon County.
(Source: P.A. 87-594.)

(225 ILCS 120/165) (from Ch. 111, par. 8301-165)
(Section scheduled to be repealed on January 1, 2028)

Sec. 165. Certification of record. The Department shall not be required to certify any record to the court, to file an answer in court, or to otherwise appear in any court in a judicial review proceeding unless and until the Department has received from the plaintiff payment of the costs of furnishing and certifying the record, which costs shall be determined by the Department. Failure on the part of the plaintiff to file a receipt in court shall be grounds for dismissal of the action. During the pendency and hearing of any and all judicial proceedings incident to the disciplinary action, the sanctions imposed upon the accused by the Department because of acts or omissions related to the delivery of direct patient care as specified in the Department's final administrative decision, shall, as a matter of public policy, remain in full force and

effect in order to protect the public pending final resolution of any of the proceedings.
(Source: P.A. 102-879, eff. 1-1-23.)

(225 ILCS 120/170) (from Ch. 111, par. 8301-170)
(Section scheduled to be repealed on January 1, 2028)

Sec. 170. Penalties. Any person who is found to have violated any provision of this Act is guilty of a Class A misdemeanor. On conviction of a second or subsequent offense, the violator shall be guilty of a Class 4 felony. All criminal fines, monies, or property collected or received by the Department under this Section or any other State or federal statute, including, but not limited to, property forfeited to the Department under Section 505 of the Illinois Controlled Substances Act or Section 85 of the Methamphetamine Control and Community Protection Act, shall be deposited into the Professional Regulation Evidence Fund.
(Source: P.A. 94-556, eff. 9-11-05.)

(225 ILCS 120/173)
(Section scheduled to be repealed on January 1, 2028)

Sec. 173. Confidentiality. All information collected by the Department in the course of an examination or investigation of a licensee or applicant, including, but not limited to, any complaint against a licensee filed with the Department and information collected to investigate any such complaint, shall be maintained for the confidential use of the Department and shall not be disclosed. The Department may not disclose the information to anyone other than law enforcement officials, other regulatory agencies that have an appropriate regulatory interest as determined by the Secretary, or a party presenting a lawful subpoena to the Department. Information and documents disclosed to a federal, State, county, or local law enforcement agency shall not be disclosed by the agency for any purpose to any other agency or person. A formal complaint filed against a licensee by the Department or any order issued by the Department against a licensee or applicant shall be a public record, except as otherwise prohibited by law.
(Source: P.A. 97-804, eff. 1-1-13.)

(225 ILCS 120/175) (from Ch. 111, par. 8301-175)
(Section scheduled to be repealed on January 1, 2028)

Sec. 175. Administrative procedure. The Illinois Administrative Procedure Act is hereby expressly adopted and incorporated as if the provisions of that Act were included in this Act, except that the provision of paragraph (d) of Section 10-65 of the Illinois Administrative Procedure Act, which provides that at hearings the licensee has the right to show compliance with all lawful requirements for retention, continuation, or renewal of the license, is specifically excluded. For the purpose of this Act, the notice required under Section 10-25 of the Administrative Procedure Act is deemed sufficient when mailed to the last known address of a party.
(Source: P.A. 87-594; 88-670, eff. 12-2-94.)

(225 ILCS 120/180) (from Ch. 111, par. 8301-180)
(Section scheduled to be repealed on January 1, 2028)

Sec. 180. Conflict of laws. In the event of a conflict between any provision of this Act and the Mental Health and Developmental Disabilities Confidentiality Act, the provisions of this Act shall govern.
(Source: P.A. 87-594.)

deposition or both, with the same fees and mileage and in the same manner as prescribed by law in judicial proceedings in civil cases in circuit courts of this State. The Department may subpoena and compel the production of documents, papers, files, books, and records in connection with any hearing or investigation.

The Secretary, hearing officer, and any member of the Board shall each have power to administer oaths to witnesses at any hearing which the Department is authorized to conduct under this Act, and any other oaths required or authorized to be administered by the Department under this Act.
(Source: P.A. 102-879, eff. 1-1-23.)

(225 ILCS 120/105) (from Ch. 111, par. 8301-105)
(Section scheduled to be repealed on January 1, 2028)

Sec. 105. Report of findings and recommendation. At the conclusion of the hearing, the Board shall present to the Secretary a written report of its findings of fact, conclusions of law, and recommendations. The report shall contain a finding whether or not the accused person violated this Act or failed to comply with the conditions required in this Act. The Board shall specify the nature of the violation or failure to comply and shall make its recommendations to the Secretary.

The report of findings of fact, conclusion of law, and recommendations of the Board shall be the basis for the Department's order for refusal or for the granting of a license or registration. The finding is not admissible in evidence against the person in a criminal prosecution brought for the violation of this Act, but the hearing and finding are not a bar to a criminal prosecution brought for the violation of this Act.
(Source: P.A. 102-879, eff. 1-1-23.)

(225 ILCS 120/110) (from Ch. 111, par. 8301-110)
(Section scheduled to be repealed on January 1, 2028)

Sec. 110. Hearing officers; appointment. Notwithstanding any other provision of this Act, the Secretary shall have the authority to appoint any attorney duly licensed to practice law in the State of Illinois to serve as the hearing officer in any action before the Board for refusal to issue or renew a license, or the discipline of a licensee. The hearing officer shall report his findings of fact, conclusions of law, and recommendations to the Board and the Secretary. The Board shall have 60 days from receipt of the report to review the report of the hearing officer and present its findings of fact, conclusions of law, and recommendations to the Secretary. If the Board fails to present its report within the 60 day period, the Secretary may issue an order based on report of the hearing officer and the record of the proceedings or issue an order remanding the matter back to the hearing officer for additional proceedings in accordance with the order. If the Secretary disagrees with the recommendation of the Board or the hearing officer, the Secretary may issue an order in contravention of the recommendation.
(Source: P.A. 102-879, eff. 1-1-23.)

(225 ILCS 120/115) (from Ch. 111, par. 8301-115)
(Section scheduled to be repealed on January 1, 2028)

Sec. 115. Motion for rehearing. In any case involving the refusal to issue, renew, or discipline of a license or registration, a copy of the Board's report shall be served upon the respondent by the Department, either personally or as provided in this Act for the service of the notice of hearing. Within 20 days after service, the respondent may present to the Department a motion in writing for a rehearing, which shall

specify the particular grounds for rehearing. If no motion for rehearing is filed, then upon the expiration of the time specified for filing a motion, or if a motion for rehearing is denied, then upon denial the Secretary may enter an order in accordance with recommendations of the Board. If the respondent orders from the reporting service and pays for a transcript of the record within the time for filing a motion for rehearing, the 20-day period within which a motion may be filed shall commence upon the delivery of the transcript to the respondent.
(Source: P.A. 102-879, eff. 1-1-23.)

(225 ILCS 120/120) (from Ch. 111, par. 8301-120)
(Section scheduled to be repealed on January 1, 2028)

Sec. 120. Rehearing by order of Secretary. Whenever the Secretary is satisfied that substantial justice has not been done in the revocation, suspension, or refusal to issue or renew a license or registration, the Secretary may order a rehearing by the same hearing office or Board.
(Source: P.A. 102-879, eff. 1-1-23.)

(225 ILCS 120/125) (from Ch. 111, par. 8301-125)
(Section scheduled to be repealed on January 1, 2028)

Sec. 125. Duties of the Board. The Board shall exercise the rights, powers, and duties which have been vested in the Board under this Act, and any other duties conferred upon the Board by law.
(Source: P.A. 102-879, eff. 1-1-23.)

(225 ILCS 120/130) (from Ch. 111, par. 8301-130)
(Section scheduled to be repealed on January 1, 2028)

Sec. 130. State liability for disciplinary action without reasonable basis. In the event that the Department's order of revocation, suspension, placing the licensee on probationary status, or other order or formal disciplinary action is without any reasonable basis, then the State of Illinois shall be liable to the injured party for those special damages suffered as a direct result of such order.
(Source: P.A. 87-594.)

(225 ILCS 120/135) (from Ch. 111, par. 8301-135)
(Section scheduled to be repealed on January 1, 2028)

Sec. 135. Disciplinary consent orders. Notwithstanding the provisions of this Act concerning the conduct of hearings and recommendations for disciplinary actions, the Secretary shall have the authority to negotiate agreements with licensees resulting in disciplinary consent orders. Consent orders may provide for any of the forms of discipline otherwise provided in this Act. Consent orders shall provide that they were not entered into a result of any coercion by the Department.
(Source: P.A. 102-879, eff. 1-1-23.)

(225 ILCS 120/140) (from Ch. 111, par. 8301-140)
(Section scheduled to be repealed on January 1, 2028)

Sec. 140. Orders; prima facie proof. An order or a certified copy thereof, over the seal of the Department and purporting to be signed by the Secretary, shall be prima facie proof that:

(a) the signature is the genuine signature of the Secretary;

(b) the Secretary is duly appointed and qualified; and

(c) the Board and its members are qualified to act.
(Source: P.A. 102-879, eff. 1-1-23.)

(225 ILCS 120/185) (from Ch. 111, par. 8301-185)
(Section scheduled to be repealed on January 1, 2028)

Sec. 185. Home rule preemption. The regulation and licensing of wholesale drug distributors are exclusive powers and functions of the State. A home rule unit may not regulate or license wholesale drug distributors. This Section is a denial and limitation of home rule powers and functions under subsection (h) of Section 6 of Article VII of the Illinois Constitution.
(Source: P.A. 87-594.)

(225 ILCS 120/195) (from Ch. 111, par. 8301-195)
(Section scheduled to be repealed on January 1, 2028)

Sec. 195. Effective date. This Act shall take effect upon becoming law.
(Source: P.A. 87-594.)

(225 ILCS 120/200)
(Section scheduled to be repealed on January 1, 2028)

Sec. 200. Drugs in shortage.

(a) For the purpose of this Section, "drug in shortage" means a drug, as defined in Section 356c of the Federal Food, Drug, and Cosmetic Act, listed on the drug shortage list maintained by the U.S. Food and Drug Administration in accordance with Section 356e of the Federal Food, Drug, and Cosmetic Act.

(b) Any person engaged in the wholesale distribution of a drug in shortage in this State must be licensed by the Department.

(c) It is unlawful for any person, other than a manufacturer, a manufacturer's exclusive distributor, a third-party logistics provider, or an authorized distributor of record, to purchase or receive a drug in shortage from any person not licensed by the Department. This subsection (c) does not apply to the return of drugs or the purchase or receipt of drugs pursuant to any of the distributions that are specifically excluded from the definition of "wholesale distribution" in Section 15 of the Wholesale Drug Distribution Licensing Act.

(d) A person found to have violated a provision of this Section shall be subject to administrative fines, orders for restitution, and orders for disgorgement.

(e) The Department shall create a centralized, searchable database of those entities licensed to engage in wholesale distribution, including manufacturers, wholesale distributors, and pharmacy distributors, to enable purchasers of a drug in shortage to easily verify the licensing status of an entity offering such drugs.

(f) The Department shall establish a system for reporting the reasonable suspicion that a violation of this Act has been committed by a distributor of a drug in shortage. Reports made through this system shall be referred to the Office of the Attorney General and the appropriate State's Attorney's office for further investigation and prosecution.

(g) The Department shall adopt rules to carry out the provisions of this Section.

(h) Nothing in this Section prohibits one hospital pharmacy from purchasing or receiving a drug in shortage from another hospital pharmacy in the event of a medical emergency.
(Source: P.A. 102-879, eff. 1-1-23.)

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Office of the Secretary of State
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# Business Entity Search

## Entity Information

| | | | |
|---|---|---|---|
| **Entity Name** | BRAINLAB, INC. | | |
| **File Number** | 62743034 | **Status** | GOODSTANDING |
| **Entity Type** | CORPORATION | **Type of Corp** | FOREIGN BCA |
| **Qualification Date (Foreign)** | 03-06-2003 | **State** | DELAWARE |
| **Duration Date** | PERPETUAL | | |
| **Annual Report Filing Date** | 04-06-2023 | **Annual Report Year** | 2023 |
| **Agent Information** | ILLINOIS CORPORATION SERVICE COMPANY<br>801 ADLAI STEVENSON DRIVE<br>SPRINGFIELD ,IL 62703-4261 | **Agent Change Date** | 10-19-2015 |

## Services and More Information

Choose a tab below to view services available to this business and more information about this business.

Purchase Master Entity Certificate of Good Standing

Purchase Assumed Name Certificate of Good Standing

Change of Registered Agent and/or Registered Office

Adopting Assumed Name

ACORD®

# CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY)
10/04/2022

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

| PRODUCER | CONTACT NAME: | |
|---|---|---|
| Aon Risk Services Central, Inc.<br>Chicago IL Office<br>200 East Randolph<br>Chicago IL 60601 USA | PHONE (A/C. No. Ext): (866) 283-7122 | FAX (A/C. No.): (800) 363-0105 |
| | E-MAIL ADDRESS: | |

| INSURED | INSURER(S) AFFORDING COVERAGE | NAIC # |
|---|---|---|
| Brainlab, Inc.<br>5 Westbrook Corporate Center<br>Suite #1000<br>Westchester IL 60154 USA | INSURER A: Property & Casualty Ins Co of Hartford | 34690 |
| | INSURER B: Trumbull Insurance Company | 27120 |
| | INSURER C: Indian Harbor Insurance Company | 36940 |
| | INSURER D: XL Select Insurance Co | 19607 |
| | INSURER E: | |
| | INSURER F: | |

**COVERAGES** **CERTIFICATE NUMBER:** 570095904934 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

| INSR LTR | TYPE OF INSURANCE | ADDL INSD | SUBR WVD | POLICY NUMBER | POLICY EFF (MM/DD/YYYY) | POLICY EXP (MM/DD/YYYY) | LIMITS | |
|---|---|---|---|---|---|---|---|---|
| C | X COMMERCIAL GENERAL LIABILITY<br>CLAIMS-MADE X OCCUR<br>GEN'L AGGREGATE LIMIT APPLIES PER:<br>X POLICY PRO-JECT LOC<br>OTHER: | | | US00011281LI22A | 10/01/2022 | 10/01/2023 | EACH OCCURRENCE<br>DAMAGE TO RENTED PREMISES (Ea occurrence)<br>MED EXP (Any one person)<br>PERSONAL & ADV INJURY<br>GENERAL AGGREGATE<br>PRODUCTS - COMP/OP AGG | $1,000,000<br>$300,000<br>$10,000<br>$1,000,000<br>$1,000,000<br>$1,000,000 |
| B | AUTOMOBILE LIABILITY<br>X ANY AUTO<br>OWNED AUTOS ONLY<br>HIRED AUTOS ONLY<br>SCHEDULED AUTOS<br>NON-OWNED AUTOS ONLY | | | 83 UEN ZV3537 | 10/01/2022 | 10/01/2023 | COMBINED SINGLE LIMIT (Ea accident)<br>BODILY INJURY ( Per person)<br>BODILY INJURY (Per accident)<br>PROPERTY DAMAGE (Per accident)<br>Medical Payments | $2,000,000<br><br><br><br>$10,000 |
| D | X UMBRELLA LIAB X OCCUR<br>EXCESS LIAB CLAIMS-MADE<br>DED X RETENTION $10,000 | | | US00011282LI22A | 10/01/2022 | 10/01/2023 | EACH OCCURRENCE<br>AGGREGATE | $4,000,000<br>$4,000,000 |
| A | WORKERS COMPENSATION AND EMPLOYERS' LIABILITY<br>ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH)<br>If yes, describe under DESCRIPTION OF OPERATIONS below | Y / N: N | N / A | 83WEAA6VRW | 10/01/2022 | 10/01/2023 | X PER STATUTE OTH-ER<br>E.L. EACH ACCIDENT<br>E.L. DISEASE-EA EMPLOYEE<br>E.L. DISEASE-POLICY LIMIT | <br>$1,000,000<br>$1,000,000<br>$1,000,000 |
| C | Cyber Liability | | | MTP003623311<br>Claims made<br>SIR applies per policy terms & conditions | 10/01/2022 | 10/01/2023 | Aggregate<br>SIR | $5,000,000<br>$250,000 |

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Evidence of Insurance.

**CERTIFICATE HOLDER**

Brainlab, Inc.
5 Westbrook Corporate Center, Ste. #1000
Westchester IL 60154 USA

**CANCELLATION**

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central, Inc.

Holder Identifier :

Certificate No : 570095904934

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The ACORD name and logo are registered marks of ACORD

# NEVADA STATE BOARD OF PHARMACY

**985 Damonte Ranch Pkwy Suite 206**
**Reno, NV 89521**
**(775) 850-1440**
**Fax: (775) 850-1444**

## PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 83BSBJA8959

Application/License No. _____

BRAINLAB, INC. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5 Westbrook Corporate Center, Ste. 1000 Westchester, IL 60154 (Address of Applicant/Principal), as PRINCIPAL, and HARTFORD FIRE INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of CT (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Hartford Plaza Hartford, CT 06155 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on June 20, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 20th day of June, 2023.

APPLICANT/PRINCIPAL
BRAINLAB, INC.

Authorized Representative

SURETY COMPANY
HARTFORD FIRE INSURANCE COMPANY

Surety Company's Representative

Derek J. Elston, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Ann Formhals

Witness Chris Troha

Countersigned by:

N/A
Nevada Resident Agent

# POWER OF ATTORNEY

*Direct Inquiries/Claims to:*
**THE HARTFORD**
**BOND, T-11**
**One Hartford Plaza**
**Hartford, Connecticut 06155**
Bond.Claims@thehartford.com
*call:* **888-266-3488** *or fax:* **860-757-5835**

**KNOW ALL PERSONS BY THESE PRESENTS THAT:**

**Agency Name:** AON RISK SERVICES CENTRAL INC
**Agency Code:** 83-553702

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [X] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [X] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois**, a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast,** a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut, (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint, ***up to the amount of*** Unlimited :

Derek J. Elston, Christopher P. Troha, Marcia K. Cesafsky, Rachel Fore, Jennifer L. Jakaitis, Bartlomiej Siepierski, Aerie Walton of CHICAGO, Illinois

their true and lawful Attorney(s)-in-Fact, each in their separate capacity if more than one is named above, to sign its name as surety(ies) only as delineated above by ☒, and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

**In Witness Whereof**, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

**STATE OF FLORIDA**
**COUNTY OF SEMINOLE** } **ss.** Lake Mary

On this 20th day of May, 2021, before me personally came Joelle LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Jessica Ciccone
My Commission HH 122280
Expires June 20, 2025

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of June 20th, 2023.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

### Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Brainlab, Inc. MDEG License # (if applicable) _____

Physical Address 5 Westbrook Corporate Center, Ste 1000

City Westchester State IL Zip 60154

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 708-409-1343 Website brainlab.com

Licensing Company Email sean.clark@brainlab.com

### Section 2: Personal Information

First Sean Middle M Last Clark

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] Grand Avenue

City Western Springs State IL Zip 60558

Telephone 708-409-1343 Email sean.clark@brainlab.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.320) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | ✓ | |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Pending Required Information (NRS 425.540) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 3: List your high school and college experience beginning with the most recent. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Joliet Catholic High School | | 08/86-06/90 | |
| Address | City | State | Zip |
| 1200 N. Larkin Ave | Joliet | IL | 60435 |
| Diploma/Degree obtained, if any | | | |
| HS Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| United States Naval Academy | | 07/90-06/94 | |
| Address | City | State | Zip |
| 121 Blake Road | Annapolis | MD | 21402 |
| Diploma/Degree obtained, if any | | | |
| BS | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 4: List your most recent job first. Include military service and volunteer work. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 06/10- present | [redacted] Grand Ave | Western Springs | IL | 60558 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Brainlab, Inc. | | | 07/01-present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 5 Westbrook Corporate Center, STE 1000 | | Westchester | IL | 60154 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 708-409-1343 | President | | 4100+ | |
| **Description of Duties** | | | | |
| Presidential duties, including oversight of all business operations | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state? | | ✓ |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline. | | ✓ |

**Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>**

This is in response to Question # _____. **Provide all the following *<u>where applicable</u>*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted) Date

I, Sean M. Clark, **certify that as the MDEG Administrator for**

Brainlab, Inc.,

**that I (initial that you have read and meet the following requirements):**

1. ___ Have a high school diploma or its equivalent;
2. ___ Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. ___ Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. ___ Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Sean M. Clark
Print Name (First, Last)

Sean M. Clark
Original Signature (electronic, copies or stamps not accepted)

20 JUN 23
Date

| Board Use Only | Date Received: 7/3/23 |
|---|---|

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

4

### Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Brainlab, Inc.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 5 Westbrook Corporate Center, Ste 1000

City Westchester State IL Zip 60154

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 708-409-1343 Website www.brainlab.com

Licensing Company Email sean.clark@brainlab.com

### Section 2: Personal Information

First Sean Middle M Last Clark

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] Grand Avenue

City Western Springs State IL Zip 60558

Telephone 708-409-1343 Email sean.clark@brainlab.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | ✓ | |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

[redacted]

| School Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Joliet Catholic High School | | | 08/86-06/90 | |
| Address | | City | State | Zip |
| 1200 N. Larkin Ave | | Joliet | IL | 60435 |
| Diploma/Degree obtained, if any | | | | |
| HS diploma | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| United States Naval Academy | | | 07/90-06/94 | |
| Address | | City | State | Zip |
| 121 Blake Road | | Annapolis | MD | 21402 |
| Diploma/Degree obtained, if any | | | | |
| BS | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |
| School Name | | | From - To (MM/YY – MM/YY | |
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |

[redacted]

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 06/10- current | [redacted] Grand Ave. | Western Springs | IL | 60558 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Brainlab, Inc. | | | 07/01-present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 5 Westbrook Corporate Center, STE 1000 | | Westchester | IL | 60454 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 708-409-1343 | President | | 4100+ | |
| **Description of Duties** | | | | |
| Presidential duties, including oversight of all business operations | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✓ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | ✓ | |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | ✓ | |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # 5 & 6. **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

From time to time in the ongoing course of business, Brainlab, Inc. is named as a defendant or is subject to a regulatory review. Brainlab has not received a judgment against it in any court nor a finding by a regulatory agency.

Original Signature (electronic, copies or stamps not accepted)

20JUN23
Date

I, Sean M. Clark, **certify that as the designated representative for**

Brainlab, Inc.,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. ___ I am at least 21 years of age;
3. ___ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ___ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ___ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ___ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ___ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Sean M. Clark

Print Name (First, Last)

Sean M. Clark

Original Signature (electronic, copies or stamps not accepted)

20JUN23

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Sean M. Clark

Print Name (First, Last)

Sean M. Clark

Original Signature (electronic, copies or stamps not accepted)

20 JUN 23

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Illinois, ss. County of Cook

I, SEAN M. CLARK, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Sean M. Clark

**Original Signature**

20 JUN 23

**Date**

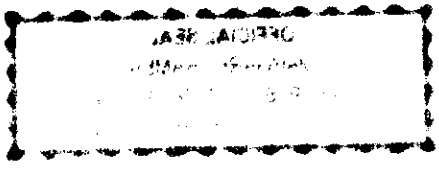
Subscribed and Sworn to before me this 20 day of June, 2023

Margaret Ramer

**Notary Public Signature**

OFFICIAL SEAL
MARGARET RAMER
NOTARY PUBLIC, STATE OF ILLINOIS
MY COMMISSION EXPIRES: 10/31/2026

**(Seal)**



| Employee List | Brainlab Inc |
|---|---|
| **Last Name** | **First Name** |
| Abrams | Jordyn |
| Al-Mahdi | Abdullah |
| Alaimo | Anthony |
| Albert III | Thomas |
| Albian | Robert |
| Alt | Maggie |
| Altobelli | Sophia |
| Amer | Samih |
| AMES | TAMRA |
| Amorjay-Ogar | Michael |
| Anderson | Kelly |
| Anderson | Erin |
| Arabia | Austin |
| Arabia | Vincent |
| Arnold | Serena |
| Askey | Sophie |
| Atiar | Afrida |
| Avallone | Joseph |
| Avila Mejia | Felipe |
| Aziz | Andrei |
| babaghayou | Mohamed Rami |
| Baca III | Arnold |
| Baez | Octavio |
| Baier | Ryan |
| Baker | Kyle |
| Banda | Chen |
| Bandukwala | Nazneen |
| Barron | Taylor |
| Baxter | Dayton |
| Beevers | Tyler |
| Belay | Sem |
| Belloeil-Marrane | Tristan |
| Benson | Danielle |
| Bergamini | Jay |
| Bode | Erika |
| Bosset | Mark |
| Boyd | James |
| Boylan | Emily |
| Brauns | William |
| Brett | Sonja |
| Brett | David |
| Brobston | Daniel |
| Brodie | Kristina |
| Brooks | Kaitlyn |
| Brown | David |
| Brown | Kellan |
| Bruseski | Mark |
| Bryan | Hanna |
| Bryant | Joshua |
| Buckelew | Andrea |
| Butler | Erin |
| Cardenas | Monica |
| Carlile | Abby |

| | |
|---|---|
| Casciano | Cameron |
| Casella | Kristen |
| Casey | Scott |
| Cassata | Dominica |
| Castaneda | Gerardo |
| Cearnal | Matthew |
| Cepkauskas | Krista |
| Cerri | Amy |
| Chandler | Jason |
| Chari | Koumudi |
| Chavez | Lawrence |
| Chigbrow | Kevin |
| Chin | Jay |
| Chiu | Kevin |
| Clark | Sean |
| Cockerham | Lindsi |
| Conforti | Frank |
| Conroy | Kevin |
| Cook | Ian |
| Cooke | Haley |
| Cooney | Sam |
| Coons | James |
| Cooper | Hayley |
| Corbin | Sabrina |
| Coubrough | Kali |
| Craig | Garett |
| Crites | Brooklynn |
| Cruz Soto | Iveth |
| Cundiff | Miranda |
| Curtin | Samantha |
| Dalton | Kimberly |
| David | Ashwin |
| davis | nicole |
| Davis | Coy |
| Demas | Eleni |
| Dhooghe | Dylan |
| Dickerson | Kristin |
| Dignan | Molly |
| Dillard | Julie |
| Donahue | Robert |
| Donnigan | Corey |
| Dorris | Maxwell |
| Dunlop | William |
| Earle | Trevor |
| Eaton | Thom |
| Ehrhart | Trenton |
| Einfalt | Robert |
| Eisenmann | Kara |
| Elsner | Henry |
| Enlow | Maximillian |
| Erickson | Chris |
| Erler | Kurt |
| Espinoza | Javier |
| Esquibel | Lindsay |
| Estrada Mercado | Karina |

| | |
|---|---|
| Estrella | Felipe |
| Evatt-Machado | Gabriel |
| Ezzell | Amanda |
| Faraci | Kennedy |
| Flaherty | Alexis |
| Flannery | Brent |
| Franca Jr. | Steven |
| Frawley | Jesse |
| Friedlander | Parker |
| Fuchs | Emily |
| Fuchs | Jay |
| Fuentes | Luis |
| Fuqua | Daniel |
| Gall III | Arthur |
| Galvez | David |
| Gedraitis | Amanda |
| Georges | Cameron |
| Glozman | Zeev |
| Goeman | Jenessa |
| Goncalves | John |
| Gonzalez | Dante |
| Goode | Henry |
| Goodfriend | Michael |
| Gordon | Ryan |
| GRIFFIN | LATOYA |
| Gronewold | Darin |
| Guthrie | Katherine |
| Guzman | Alfredo |
| Han | Keri |
| Hand | Josephine |
| Hanson | Meredith |
| Harrison | David |
| Harvey | Caroline |
| Hastings | Bryan |
| Haukas | Andreas |
| Hearin | John |
| Hemmig | Brianna |
| Hemphill | Jeffrey |
| Henderson | Steven |
| Herrmann | Maria |
| Ho | Michael |
| Hoang | Dustin |
| Hogan | Daniel |
| Hollfelder | Owen |
| Hollfelder | Jennifer |
| Horch | Michael |
| Houghton | Caitlin |
| Hussaini | Syed Obaid |
| Hutsler | Christina |
| Ignasiak | Kristina |
| Isom | Eric |
| Jacobs | Chad |
| Jacobs | William |
| Jadhav | Sreyash |
| Jensen | Erik |

| | |
|---|---|
| Jhaveri | Dweep |
| John | Tiara |
| John | Lucas |
| jonas | neil |
| Keglovich | Michael |
| Keinath | Carolyn |
| Keith | Brian |
| Kelly | Ryan |
| Kemp | Chris |
| Kennedy | Frank |
| Kiley | Michelle |
| Killelea | Kane |
| Kim | Kyeimin |
| Kim | Henry |
| King | Mallory |
| King | Alex |
| Klein | Heather |
| Kotori | Hersi |
| Koziatek | Karen |
| Krantz | Amanda |
| Krill | Andrew |
| Labate | Laura |
| Lacirignola | John |
| Landers | Sophie |
| Lapinski | Tanya |
| LaRocco | Nicholas |
| Lawrence | Jack |
| Leblanc | Donald |
| Lee | Kolby |
| Leong | Joshua |
| Lien | Jesse |
| Linebaugh | Eric |
| Ljungqvist | Rebecca |
| Llewellyn | Brandie |
| Loomis | Lauren |
| Lopez Burboa | Yuliana |
| Lopriore | Alexis |
| Loushin | Kevin |
| Luby | Skyler |
| Luke | Caitlyn |
| Lunsford | Jeffery |
| Luttrell | Natalie |
| Lwanga | Peter |
| Macero | Miles |
| Machado | Andres |
| Magera | Luke |
| Mahajan | Ninad |
| Mahoney | Jessica |
| Malek | Paxton |
| Malik | Krutika |
| Malle | Nikhil |
| Marikian | Jennifer |
| Markovic | Ruzica |
| Marley | Bernadette |
| Maronic | Michael |

| | |
|---|---|
| Martin | Grace |
| Martinez | Mark |
| Martinez | Jeannette |
| Masso Jr | Peter |
| Mauger | Abigail |
| Maxwell | Brian |
| McDaniel | Logan |
| McFadden | Connor |
| Mecham | Kyle |
| Medina | Santos |
| Melger | Thomas |
| Melman | Menashe |
| Meyer | Gabrielle |
| Meyer | Christopher |
| Meyst | Laura |
| Michaud | Brandon |
| Minick | Samuel |
| Mohr | Jocelyn |
| Morgan | Shannon |
| Morrow | Ashleigh |
| Moser | Florian |
| Moses | Michael |
| Moss | Taylor |
| Mueh | Sarah |
| Muehlethaler | Katyann |
| Murphy | Patrick |
| Murray | John |
| Muskat | James |
| Myers | Matthew |
| Neagu | Alexandru |
| Neff | Emily |
| Neil | Sterling |
| Neil | Paul |
| Nelson | Keith |
| Nelson | Evan |
| Newell | Alex |
| Nguyen | Jimmy |
| Nicholas | Stuart |
| Nichting | Blake |
| Noel | Amanda |
| Noorani | Shezaan |
| Norfleet | Eric |
| Novak | Corey |
| O'Driscoll | James |
| Ochoa | Jose |
| Olson | Jake |
| Otero | Silas |
| Owaisi | Moin |
| Oweimrin | Mazen |
| Ozinci | Erin |
| Palacios Lizarraga | Patricia |
| Panning | Micah |
| Paoliello | Philip |
| Parker | Morgan |
| Pascarella | Maura |

| | |
|---|---|
| Patel | Anjaly |
| Patel | Darshan |
| Payanoff | Nicholas |
| Payton | James |
| Pazoles | Heather |
| Pennant | Phillip |
| Pham | Tatiana |
| Philip | Nicole |
| Philip | Aji |
| Plaisance | Matthew |
| Plemmons | Grace |
| Polak | Courtney |
| Pratt | William |
| Prideaux | Dasani |
| Ramer | Margaret |
| Ramos | Laura |
| Ramos | Alejandro |
| Rateb | Alexander |
| Reals | Jeff |
| Richardson | Brian |
| Richert | Ariana |
| Riley | Robert |
| Rivera | Jose Luis |
| Rivera | Daniel |
| Robbins | Mark |
| Robles | Daniel |
| Rodas | Conrad |
| Roers | Michelle |
| Rogers | Renee |
| Roggeman | David |
| Romero | Randy |
| Rosenberg | Scott |
| Rost | Niels |
| Ryan | Matthew |
| Sananikone | Sisoumang |
| Sardo | Matt |
| Schatteman | Joshua |
| Scheer | Ronald |
| Schmitz | Ben |
| Schober | Lillian |
| Schrier | Todd |
| Schuett | Ferdinand |
| Schwartz | Richard |
| Sciacca | Frank |
| Seale | Jordan |
| Senesac | Mark |
| Seymour | Sarah |
| Sherwin Tippins | Colleen |
| Shin | Soon |
| Shirzad | Jahveed |
| Shivers | Olivia |
| Short | Andrew |
| Silverman | Bernard |
| Simmons | Megan |
| Simperingham | Ian |

| | |
|---|---|
| Simpson | Sean |
| Sleezer | Lauren |
| Smith | Tyler |
| Smith | Michael |
| Sobieski | Talisa |
| Solis | Jeanette |
| Somashekar | Ashish |
| Soukup | Amanda |
| Spatafora | Kinslee |
| Spiros | Anna |
| Sprague | Daniel |
| Stalf | Blake |
| Steele | Luke |
| Steffy | Daniel |
| Strollo | Matthew |
| Sweet Robinson | Holly |
| Swindle | Summer |
| Tannehill | Michael |
| Tente | Victor |
| Thomas | Mathew |
| Thompson | Megan Milagros |
| Threeton | Dominick |
| Tillett | James |
| Tiong | Wesley |
| Title | Wallace |
| Tomlinson | Michael |
| Torres | Edgar |
| Tsvetkov | Mikhail |
| Tyrrell | Christina |
| Uyeno | Sherman |
| Valcu | Bogdan |
| Van Zandbergen | Ben |
| Varlotta | Amanda |
| Vashisth | Amit |
| Venkataramanan | Anjhana |
| Verard | Debbra |
| Vie | Rachel |
| Vilela da Silva | Jose |
| Voien | Erica |
| Vollink | Emily |
| Wade | James |
| Waid | Andrew |
| Walker | James |
| Wang | Ching kai |
| Ward | Joyce |
| Watson | Kasha |
| Wawrzyniak | Branden |
| Weaver | Sean |
| Webster | Virginia |
| Weilage | Tanner |
| West | Charles |
| Westaway | Kacie |
| Westerhold | Kristin |
| Wheat | Joshua |
| White | Lenise |

| | |
|---|---|
| Whitfield | Brooke |
| Widdifield | Morgan |
| Widdifield | Samuel |
| Widdifield | Steven |
| Willett | Blaine |
| Williams | Daryl |
| Williams | Hannah |
| Williams | Jason |
| Willis | Luke |
| Wimberger | Maximillian |
| Winkler | Travis |
| Wise | Carrie |
| Wivholm | Brandon |
| Wright | Natalie |
| Wu | Yuwei |
| Zamora | Alondra |
| Zavala | Stacy |
| Zhang | Charles |
| Ziegler | Alexander |

# 4F

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application
## Non-Refundable $1,000 Fee

Rev (08/17/2022)

| Where is the facility located? | | ☐ Nevada ■ Out-of-State |
|---|---|---|
| **Type of Application (check applicable box)** | | **Wholesaler Business Type (check applicable box)** |
| ■ New Wholesaler<br>☐ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH _____ | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: Cerapedics Inc.

Physical Address: 11025 Dover Street, Suite 1600

City: Westminster State: CO Zip: 80021

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 303-974-6275 Website: www.cerapedics.com

Name of Designated Representative (DR): Matthew Thomas

Licensing Company Email: contractdetails@cerapedics.com DR Email: mthomas@cerapedics.com

| Entities the Wholesaler will Serve (✓ all applicable) | Products to be Handled or Wholesaled (✓ all applicable) | Type of Wholesaling (✓ all applicable) |
|---|---|---|
| ☐ Pharmacies | ☐ Dangerous Drugs | ■ Manufacturer |
| ☐ Practitioners | ☐ Controlled Substances | ☐ Repacker |
| ■ Hospitals | ■ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ☐ Wholesalers | ☐ Others: | ☐ Warehouse |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ☐ Others: | | ☐ Others: |

| Section 2: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✓ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | ✓ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | ✓ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✓ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # _____. **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

Date

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

**Name:** _____

**Address:** _____ **City:** _____ **State:** _____ **Zip:** _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

**Name:** _____

**Address:** _____ **City:** _____ **State:** _____ **Zip:** _____

**Section 4: Publicly Traded Corporation**

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: Delaware

Parent Company (if any): _____

Corporation/Organization Name: Cerapedics Inc.

Mailing Address: 11025 Dover Street, Suite 1600

City: Westminster State: CO Zip: 80021

Telephone: 303-974-6275 Email: kburke@cerapedics.com

Contact Person Name: Kimberly Burke

**Section 6: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

**Section 7: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | ✓ |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | ✓ | |
| 1. Copy of FDA registration<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partnership | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** | | ✓ | | |
| • **List of all partners and their percent ownership.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Cerapedics Inc.

Facility Name

Matthew Thomas

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

July 19, 2023

Date

| Board Use Only | Date Received: 7/20/23 | Amount: 1000-CC ✓ 7/24/23 |
|---|---|---|

**NEVADA STATE BOARD OF PHARMACY**
**Cerapedics WHOLESALER APPLICATION**
**Section 9**

## List of all Officers and Directors

| Name | Title |
|---|---|
| Valeska Schroeder | Chief Executive Officer |
| Ajay Bansal | Chief Financial Officer |
| John Cherf, MD | Chief Medical Officer |
| Mani Gopal | Chief Operating Officer |
| Kimberly Burke | General Counsel |
| Jeff Marx | Chief Scientific Officer |
| Matthew Thomas | Chief Commercial Officer |
| Kelley Komula | VP of Global Commercial Operations & Development |
| Jerome Connor | Vice President Of Research and Development |
| Genevra Enna | Vice President, Controller |
| Roger White | Vice President Of Regulatory |
| James Delor | VP, Sales Education & Development, General Manager |
| Kim Schelble | Vice President Strategy, Global Upstream Marketing |
| Holly Smith | Vice President, Operations |
| Lori Hays | VP of Regulatory |
| Harold Johnson | VP of Human Resources |
| Josef Vance | VP, Sales Operations & Training |
| Mickey Brown | VP, Access and Reimbursement |
| Robert Flynn | Area Vice President |
| Tom Anderson | Area Vice President |
| Frank Destefano | Area Vice President |
| Sean Lesage | Area Vice President |
| Delia Cook | Sr. Director, Marketing Communications |
| Rick Preusse | Sr Director, Sales Education & Training |
| Katherine Davis | Director, Research & Development |
| Tim Benoit-Ledoux | Associate General Council |
| Lauren Thal | Senior Director, Compliance Officer |
| Steven Ulrich | Senior Director of Strategy & Analytics |
| Robert Shek | Area Director |
| Aaron Golliday | Area Director |
| Patrick Bohrman | Director, US Sales Operations |
| Thomas Nardi | Senior Director Of Finance And It Systems |
| Heath Thompson | Senior Director of Strategic Accounts, Americas |
| Stacy Hailey | Senior Director of Global Medical Education |
| Philip Ake | Director, PMO |
| Brian Ranck | Senior Director, Innovation Core Team Leader |
| Marissa Caputo | Director of Global Medical Education Strategy & Pr |
| Katherine Lakstins | Senior Medical Science Liaison |
| Timothy Spina | Area Director |

**NEVADA STATE BOARD OF PHARMACY**
**Cerapedics WHOLESALER APPLICATION**
**Section 9**

| | |
|---|---|
| Luis Ayllon | Sr Director of Product Innovation |
| Kristen Toutant | Director, Global Strategy & Upstream Marketing |
| Keith Price | Director, Product Management (P15 & Matrix) |
| Cody Hanson | Director, Quality |
| Rebecca Helpert | Director of Commercial Operations |
| Nicholas Kameron | Director, IT |
| Roezina Barton | Director, Global Contracts & Commercial Excellence |
| Alanya Mccomis | Director Of Hr And Employee Relations |
| Avosuahi Aliyu | Assistant Controller |
| Javier Camano | Director, Global Innovation |
| Greg Jackson | Sr Dir, Strategic Accounts |
| Patrick Miller | Dir, Enterprise Applications |
| Vinny Guarino | Dir, National Distributor Development |
| TC Thompson | Director, Logistics and Safety |
| Matt Reece | Director, Facilities & Engineering |

**List of all corporation shareholders and their percentage ownership.**

| | |
|---|---|
| KCK LTD | 55.33% |
| NGN BioMed Opportunity II, LP | 11.33% |
| MedImmune Ventures, Inc. | 8.12% |
| Grafting LLC | 7.28% |
| KOFA Healthcare, LLC | 5.17% |
| Revelation Healthcare Fund I, L.P. | 4.72% |
| Former Employees | 4.27% |
| Current Management / Employees | 3.49% |
| Consultants / Advisors | 0.18% |
| L. Habas | 0.10% |

**Certificate of Corporate Status or Certificate of Good Standing**
(attached)

**Designated Representative form**
(attached)

**As of 6.30.23**
**List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** (attachments)

- Lender – SRL Capital Partner

**NEVADA STATE BOARD OF PHARMACY**
**Cerapedics WHOLESALER APPLICATION**
**Section 9**

**Cerapedics FDA PMA**
(attached)

**Medical Devices, Equipment and Gases (MDEG) Administrator form**
(attached)

---

**CREDIT CARD PAYMENT**

PLEASE PROVIDE A RECEIPT OF THE CREDIT CARD TRANSACTION TO contractdetails@cerapedics.com

# OFFICE OF THE SECRETARY OF STATE
# OF THE STATE OF COLORADO

# CERTIFICATE OF FACT OF GOOD STANDING

I, Jena Griswold, as the Secretary of State of the State of Colorado, hereby certify that, according to the records of this office,

Cerapedics Inc.

is an entity formed or registered under the law of Delaware , has complied with all applicable requirements of this office, and is in good standing with this office. This entity has been assigned entity identification number 20071175854 .

This certificate reflects facts established or disclosed by documents delivered to this office on paper through 02/22/2023 that have been posted, and by documents delivered to this office electronically through 02/23/2023 @ 16:04:52 .

I have affixed hereto the Great Seal of the State of Colorado and duly generated, executed, and issued this official certificate at Denver, Colorado on 02/23/2023 @ 16:04:52 in accordance with applicable law. This certificate is assigned Confirmation Number 14725301 .

Jena Griswold

Secretary of State of the State of Colorado

**********End of Certificate**********

*Notice: A certificate issued electronically from the Colorado Secretary of State's website is fully and immediately valid and effective. However, as an option, the issuance and validity of a certificate obtained electronically may be established by visiting the Validate a Certificate page of the Secretary of State's website, https://www.coloradosos.gov/biz/CertificateSearchCriteria.do entering the certificate's confirmation number displayed on the certificate, and following the instructions displayed. Confirming the issuance of a certificate is merely optional and is not necessary to the valid and effective issuance of a certificate. For more information, visit our website, https://www.coloradosos.gov click "Businesses, trademarks, trade names" and select "Frequently Asked Questions."*

# Establishment Registration & Device Listing



New Search | Back To Search Results

**Establishment:**
Cerapedics, Inc.
11025 Dover Street
Suite 1600
Westminster, CO 80021
**Registration Number:** 3007155473
**FEI Number*:** 3007155473
**Status:** Active
**Date Of Registration Status:** 2023

**Owner/Operator:**
Cerapedics, Inc.
11025 Dover Street
Suite 1600
Westminster, CO US 80021
**Owner/Operator Number:** 10026681

**Official Correspondent:**
Cody Hanson
11025 Dover St Suite 1600
Westminster, CO 80021
**Phone:** 1-303-9746275

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Page Last Updated: 07/24/2023
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

# NEVADA STATE BOARD OF PHARMACY
# Cerapedics WHOLESALER APPLICATION - Section 8

## FDA Registration

### Annual Registration Successful

Facility: Cerapedics, Inc , Westminster, Colorado, UNITED STATES

You have successfully updated your registration and listing information for 2023

Your registration will be valid through Dec 31, 2023

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2023.

***Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.***

You may contact the FDA with any questions at reglist@cdrh.fda.gov.

**The Owner/Operator Number for this Registration is: 10026681.**

**Facility Information**

**Registration Number:**
**3007155473**
**Initial Importer:**
**N**
**Facility Name:**
**Cerapedics, Inc.**
**Legal Name:**
**Address:**
**11025 Dover Street, Suite 1600**
**Westminster, Colorado, 80021, UNITED STATES**
**DUNS Number:**
**Foreign Trade Zone:**
**N**
**Facility URL:**
**Other Business Trade Name(s):**
**Establishment located on a campus:**

**Owner/Operator Information**

**Owner/Operator Number:**
**10026681**
**Contact Name:**
**Cody Hanson**
**Company:**
**CERAPEDICS, INC.**
**Address:**
**11025 Dover Street, Suite 1600**
**Westminster, COLORADO, 80021, UNITED STATES**
**Telephone:**
**303 - 9746275**
**Fax:**
**303 - 9746285**
**E-mail:**
**chanson@cerapedics.com**
**DUNS Number:**

**Official Correspondent Information**

**Contact Name:**
**Cody Hanson**
**Company:**
**CERAPEDICS, INC.**
**Address:**
**11025 Dover St Suite 1600**
**Westminster, COLORADO, 80021, UNITED STATES**
**Telephone:**
**1 - 303 - 9746275**
**Fax:**
**-**
**E-mail:**
**regulatory@cerapedics.com**
**DUNS Number:**

**Device Listings**

| Listing Number | Premarket Submission Number | Premarket Submission Type | Product Code(s) | Device Name(s) | Activities |
|---|---|---|---|---|---|
| D256111 | P140019 | | NOX | Filler, bone void, synthetic peptide | Manufacturer<br>Complaint File Establishment |
| D057027 | | pma | MBS | Filler, bone void, non-osteoinduction | U.S. Manufacturer of Export Only Devices |

**Date of Initial Registration: 2008-08-11 16:29:15.0**

## Surety Bond
(attached)

ACORD®

# CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 04/21/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

| PRODUCER | CONTACT NAME: Allen Jenkins Jr. | |
|---|---|---|
| Britton Gallagher<br>One Cleveland Center, Floor 30<br>1375 East 9th Street<br>Cleveland OH 44114 | PHONE (A/C, No, Ext): (216) 658-7850 | FAX (A/C, No): (216) 658-7101 |
| | E-MAIL ADDRESS: allen.jenkins@brittongallagher.com | |

| INSURED | INSURER(S) AFFORDING COVERAGE | NAIC # |
|---|---|---|
| Cerapedics Inc.<br>11025 Dover St., Suite 1600<br>Westminister CO 80021 | INSURER A: Gemini Insurance Company | 10833 |
| | INSURER B: StarNet Insurance Company | 40045 |
| | INSURER C: Berkley National Insurance Company | 32603 |
| | INSURER D: | |
| | INSURER E: | |
| | INSURER F: | |

**COVERAGES** **CERTIFICATE NUMBER:** 23/24 LIAB **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

| INSR LTR | TYPE OF INSURANCE | ADDL INSD | SUBR WVD | POLICY NUMBER | POLICY EFF (MM/DD/YYYY) | POLICY EXP (MM/DD/YYYY) | LIMITS | |
|---|---|---|---|---|---|---|---|---|
| A | [X] COMMERCIAL GENERAL LIABILITY<br>[ ] CLAIMS-MADE [X] OCCUR<br>GEN'L AGGREGATE LIMIT APPLIES PER:<br>[X] POLICY [ ] PRO-JECT [ ] LOC<br>[ ] OTHER: | | | GL_15494-6 | 04/24/2023 | 04/24/2024 | EACH OCCURRENCE | $ 1,000,000 |
| | | | | | | | DAMAGE TO RENTED PREMISES (Ea occurrence) | $ 1,000,000 |
| | | | | | | | MED EXP (Any one person) | $ 5,000 |
| | | | | | | | PERSONAL & ADV INJURY | $ 1,000,000 |
| | | | | | | | GENERAL AGGREGATE | $ 2,000,000 |
| | | | | | | | PRODUCTS - COMP/OP AGG | $ see below |
| | | | | | | | | $ |
| B | AUTOMOBILE LIABILITY<br>[ ] ANY AUTO<br>[ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS<br>[X] HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY | | | LCA 5056478-13 | 04/24/2023 | 04/24/2024 | COMBINED SINGLE LIMIT (Ea accident) | $ 1,000,000 |
| | | | | | | | BODILY INJURY (Per person) | $ |
| | | | | | | | BODILY INJURY (Per accident) | $ |
| | | | | | | | PROPERTY DAMAGE (Per accident) | $ |
| | | | | | | | | $ |
| C | [ ] UMBRELLA LIAB [X] OCCUR<br>[X] EXCESS LIAB [ ] CLAIMS-MADE<br>[ ] DED [X] RETENTION $ 0 | | | LNP 5046074-15 | 04/24/2023 | 04/24/2024 | EACH OCCURRENCE | $ 9,000,000 |
| | | | | | | | AGGREGATE | $ 9,000,000 |
| | | | | | | | | $ |
| C | WORKERS COMPENSATION AND EMPLOYERS' LIABILITY<br>ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y / N [ ]<br>(Mandatory in NH)<br>If yes, describe under DESCRIPTION OF OPERATIONS below | N / A | | LWC 5068317-10 | 04/24/2023 | 04/24/2024 | [X] PER STATUTE [ ] OTH-ER | |
| | | | | | | | E.L. EACH ACCIDENT | $ 1,000,000 |
| | | | | | | | E.L. DISEASE - EA EMPLOYEE | $ 1,000,000 |
| | | | | | | | E.L. DISEASE - POLICY LIMIT | $ 1,000,000 |
| A | Products - Comp/Op<br>Clinical Trial | | | GL_15494-6 | 04/24/2023 | 04/24/2024 | Aggregate | $10,000,000 |

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Products Liability is a claims-made policy; retro date is 02/01/2006.

Policy# GL_15494-4: Clinical Trial Aggregate Limit - claims made = $5,000,000 (with $50,000 per claim/$250,000 Aggregate deductible)

**CERTIFICATE HOLDER**

For Informational Purposes Only

**CANCELLATION**

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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The ACORD name and logo are registered marks of ACORD

# Additional Named Insureds

| Other Named Insureds | |
|---|---|
| Cerapedics Canada Corp. | Additional Named Insured |


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# NEVADA STATE BOARD OF PHARMACY

**985 Damonte Ranch Pkwy Suite 206**
**Reno, NV 89521**
**(775) 850-1440**
**Fax: (775) 850-1444**

## PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 100117882

Application/License No. _____

Cerapedics Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 11025 Dover Street Suite 1600 Westminster, CO 80021 (Address of Applicant/Principal), as PRINCIPAL, and Merchants Bonding Company (Mutual) (Surety Company), a corporation organized under the laws of the state of Iowa (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 6700 Westown Parkway, West Des Moines, IA 50266 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on June 15, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 15th day of June, 2024.

APPLICANT/PRINCIPAL

Cerapedics Inc.

Authorized Representative

SURETY COMPANY

Merchants Bonding Company (Mutual)

Surety Company's Representative

, Attorney-in-fact

Kristin L Salazar

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

LP 4229 NV (5/21)

MERCHANTS
BONDING COMPANY™

# POWER OF ATTORNEY

Know All Persons By These Presents, that MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., both being corporations of the State of Iowa, d/b/a Merchants National Indemnity Company (in California only) (herein collectively called the "Companies") do hereby make, constitute and appoint, individually,

**Kristin L Salazar**

their true and lawful Attorney(s)-in-Fact, to sign its name as surety(ies) and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

This Power-of-Attorney is granted and is signed and sealed by facsimile under and by authority of the following By-Laws adopted by the Board of Directors of Merchants Bonding Company (Mutual) on April 23, 2011 and amended August 14, 2015 and adopted by the Board of Directors of Merchants National Bonding, Inc., on October 16, 2015.

"The President, Secretary, Treasurer, or any Assistant Treasurer or any Assistant Secretary or any Vice President shall have power and authority to appoint Attorneys-in-Fact, and to authorize them to execute on behalf of the Company, and attach the seal of the Company thereto, bonds and undertakings, recognizances, contracts of indemnity and other writings obligatory in the nature thereof."

"The signature of any authorized officer and the seal of the Company may be affixed by facsimile or electronic transmission to any Power of Attorney or Certification thereof authorizing the execution and delivery of any bond, undertaking, recognizance, or other suretyship obligations of the Company, and such signature and seal when so used shall have the same force and effect as though manually fixed."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and authority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner-Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

In Witness Whereof, the Companies have caused this instrument to be signed and sealed this 15th day of June , 2024 .

MERCHANTS NATIONAL BONDING, INC. -o- INCORPORATED -o- 2003

MERCHANTS BONDING COMPANY (MUTUAL) -o- INCORPORATED -o- 1933

**MERCHANTS BONDING COMPANY (MUTUAL)**
**MERCHANTS NATIONAL BONDING, INC.**
**d/b/a MERCHANTS NATIONAL INDEMNITY COMPANY**

By Larry Taylor
*President*

STATE OF IOWA
COUNTY OF DALLAS ss.

On this 15th day of June , 2024 , before me appeared Larry Taylor, to me personally known, who being by me duly sworn did say that he is President of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., and that the seals affixed to the foregoing instrument are the Corporate Seals of the Companies; and that the said instrument was signed and sealed in behalf of the Companies by authority of their respective Boards of Directors.

NOTARIAL SEAL IOWA
Kim Lee
Commission Number 702737
My Commission Expires
April 14, 2024

Kim Lee
*Notary Public*

(Expiration of notary's commission
does not invalidate this instrument)

I, William Warner, Jr., Secretary of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., do hereby certify that the above and foregoing is a true and correct copy of the POWER-OF-ATTORNEY executed by said Companies, which is still in full force and effect and has not been amended or revoked.

In Witness Whereof, I have hereunto set my hand and affixed the seal of the Companies on this 15th day of June , 2024 .

MERCHANTS NATIONAL BONDING, INC. -o- INCORPORATED -o- 2003

MERCHANTS BONDING COMPANY (MUTUAL) -o- INCORPORATED -o- 1933

William Warner Jr.
*Secretary*

POA 0018 (10/22)

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

### Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Cerapedics Inc. MDEG License # (if applicable) _____

Physical Address 11025 Dover Street, Suite 1600

City Westminster State CO Zip 80021

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 303-974-6275 Website www.cerapedics.com

Licensing Company Email contractdetails@cerapedics.com

### Section 2: Personal Information

First Matt Middle _____ Last Thomas

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] W Hwy 14 [redacted]

City Spearfish State SD Zip 57783

Telephone [redacted] Email mthomas@cerapedics.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.120) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✓ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Carnegie Mellon University - Tepper School of Business | | 1992-1994 | |
| **Address** | **City** | **State** | **Zip** |
| 5000 Forbes Avenue | Pittsburgh | PA | 15213 |
| **Diploma/Degree obtained, if any** | | | |
| MBA Marketing | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| Carnegie Mellon University | | 1992-1994 | |
| **Address** | **City** | **State** | **Zip** |
| 5000 Forbes Avenue | Pittsburgh | PA | 15213 |
| **Diploma/Degree obtained, if any** | | | |
| MBA | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| University of Utah | | 1991-1992 | |
| **Address** | **City** | **State** | **Zip** |
| 201 President's Circle | Salt Lake City | UT | 84112 |
| **Diploma/Degree obtained, if any** | | | |
| BS, Economics | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| The Johns Hopkins University | | 1987-1988 | |
| **Address** | **City** | **State** | **Zip** |
| | Baltimore | MD | 21218 |
| **Diploma/Degree obtained, if any** | | | |
| | | | |
| **School Name** | | **From - To (MM/YY – MM/YY** | |
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 09/2022-current | [redacted]W Central Ave [redacted] | Westminster | CO | 80031 |
| 2018-current | [redacted]W Highway #14 [redacted] | Spearfish | SD | 57783 |
| 2018-current | [redacted] E Fence Post Road | Fruit Heights | UT | 84037 |
| 2011-2018 | [redacted] Rocky Joe Dr | Collierville | TN | 38017 |
| | | | | |
| | | | | |
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**Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. [NAC 639.694]**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Cerapedics | | | 12/14/2020 | |
| Business Address | | City | State | Zip |
| 11025 Dover St #1600 | | Westminster | CO | 80021 |
| Phone | Title | | Number of Employed Hours | |
| 303.974.6275 | Chief Commercial Officer | | 5080 ✓ | |
| Description of Duties | | | | |
| Manage sales and distribution | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| | | | | |
| Phone | Title | | Number of Employed Hours | |
| | | | | |
| Description of Duties | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| | | | | |
| Phone | Title | | Number of Employed Hours | |
| | | | | |
| Description of Duties | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| | | | | |
| Phone | Title | | Number of Employed Hours | |
| | | | | |
| Description of Duties | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| | | | | |
| Phone | Title | | Number of Employed Hours | |
| | | | | |
| Description of Duties | | | | |
| | | | | |

Continue on next page if additional space is needed.

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state? | | ✓ |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline. | | ✓ |

**Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>**

**This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

Date 5/18/23

I, Matthew Thomas, **certify that as the MDEG Administrator for**

Cerapedics, Inc.,

**that I (initial that you have read and meet the following requirements):**

1. MFT Have a high school diploma or its equivalent;
2. MFT Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MFT Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MFT Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Matthew Thomas
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5.18.2023
Date

| Board Use Only | Date Received: |
|---|---|

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

### Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Cerapedics Inc.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 11025 Dover Street, Suite 1600

City Westminster State CO Zip 80021

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 303-974-6275 Website www.cerapedics.com

Licensing Company Email contractdetails@cerapedics.com

### Section 2: Personal Information

First Matthew Middle F Last Thomas

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted] W Hwy 14 [redacted]

City Spearfish State SD Zip 57783

Telephone [redacted] Email mthomas@cerapedics.com

Are you a citizen of the United States? ■ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, 425.540, 425.560) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✓ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Carnegie Mellon University - Tepper School of Business | | 1992-1994 | |
| **Address** | **City** | **State** | **Zip** |
| 5000 Forbes Avenue | Pittsburgh | PA | 15213 |
| **Diploma/Degree obtained, if any** | | | |
| MBA Marketing | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| Carnegie Mellon University | | 1992-1994 | |
| **Address** | **City** | **State** | **Zip** |
| 5000 Forbes Avenue | Pittsburgh | PA | 15213 |
| **Diploma/Degree obtained, if any** | | | |
| MBA | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| University of Utah | | 1991-1992 | |
| **Address** | **City** | **State** | **Zip** |
| 201 President's Circle | Salt Lake City | UT | 84112 |
| **Diploma/Degree obtained, if any** | | | |
| BS, Economics | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| The Johns Hopkins University | | 1987-1988 | |
| **Address** | **City** | **State** | **Zip** |
| | Baltimore | MD | 21218 |
| **Diploma/Degree obtained, if any** | | | |
| | | | |
| **School Name** | | **From - To (MM/YY – MM/YY** | |
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 09/2022 - current | [redacted] W Central Ave #[redacted] | Westminster | CO | 80031 |
| 2018 - current | [redacted] W Highway #14 #[redacted] | Spearfish | SD | 57783 |
| 2018 - current | [redacted] E Fence Post Road | Fruit Heights | UT | 84037 |
| 2011-2018 | [redacted] Rocky Joe Dr | Collierville | TN | 38017 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAIC 4461 5005) or wholesales (NAIC 4234 5050) in a capacity related to the dispersing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Cerapedics | | | 12/14/2020 | |
| Business Address | | City | State | Zip |
| 11025 Dover St #1600 | | Westminster | CO | 80021 |
| Phone | Title | | Number of Employed Hours | |
| 303.974.6275 | Chief Commercial Officer | | 4800 | |
| Description of Duties | | | | |
| Manage sales and distribution, marketing and customer service | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Medtronic | | | 11/02 - 12/20 | |
| Business Address | | City | State | Zip |
| 710 Medtronic Parkway | | Minneapolis | MN | 55432 |
| Phone | Title | | Number of Employed Hours | |
| 763-514-4000 | General Manager&Vice President, Stim&Early Intervention | | 37,440 | |
| Description of Duties | | | | |
| Manage sales and distribution | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| | | | | |
| Phone | Title | | Number of Employed Hours | |
| | | | | |
| Description of Duties | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| | | | | |
| Phone | Title | | Number of Employed Hours | |
| | | | | |
| Description of Duties | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| | | | | |
| Phone | Title | | Number of Employed Hours | |
| | | | | |
| Description of Duties | | | | |
| | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

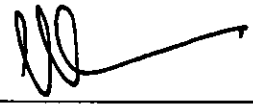
| Section 3: Arrests, Convictions, Litigations, Arbitrations | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✓ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✓ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✓ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✓ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question #** N/A **. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**



Original Signature (electronic, copies or stamps not accepted)

3/31/2023

Date

I, Matthew Thomas, **certify that as the designated representative for**

Cerapedics Inc.,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. MFT I am at least 21 years of age;
3. MFT I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MFT I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MFT I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MFT I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MFT I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Matthew Thomas

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3-31-2023

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Matthew Thomas

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3-31-2023

Date

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**Please have this section completed in the presence of a Notary Public.**

State of Colorado, ss. County of Jefferson

I, Matthew Thomas, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

3/31/2023

**Date**

Subscribed and Sworn to before me this 31st day of March.

**Notary Public Signature**

APRIL M GREEN
Notary Public
State of Colorado
Notary ID # 20044001344
My Commission Expires 01-13-2026

**(Seal)**

**EMPLOYEE POSITION LIST**

| Last Name | Preferred/First Name | Department Description | Employment Type Description | Job Title (PIT) |
|---|---|---|---|---|
| Marek | Carolyn | 4031 - SALES | Regular Full Time | Regional Sales Manager |
| Williams | Jeff | 3023 - MAN | Regular Full Time | Manufacturing Technician II |
| Dygert | Mark | 3021 - CUSTSRVC | Regular Full Time | Customer Service Analyst |
| Spina | Timothy | 4031 - SALES | Regular Full Time | Area Director |
| Komula | Kelley | 4042 - Strategic Accounts & Contracting | Regular Full Time | VP of Strategic Accounts, Contracting, & Customer |
| Gasseling | Deanna | 3021 - CUSTSRVC | Regular Full Time | Customer Service Analyst |
| Lujan Saenz | Nancy | 3023 - MAN | Regular Full Time | Manufacturing Technician II |
| Price | Jayme | 4042 - Strategic Accounts & Contracting | Regular Full Time | Strategic Accounts Manager |
| Sanford | Timothy | 4031 - SALES | Regular Full Time | Senior Regional Sales Manager |
| Demar | Paige | 3021 - CUSTSRVC | Regular Full Time | Customer Service Analyst |
| Hailey | Stacy | 4045 - Medical Affairs & Education | Regular Full Time | Senior Director of Global Medical Education |
| Helpert | Rebecca | 4042 - Strategic Accounts & Contracting | Regular Full Time | Director of Commercial Operations |
| Ranck | Brian | 4040 - Global Innovation | Regular Full Time | Senior Director, Innovation Core Team Leader |
| Magnuson | Mike | 1003 - FAC | Regular Full Time | Maintenance Tech Iii |
| Hogan | Will | 4031 - SALES | Regular Full Time | Regional Sales Manager |
| Gunnels | Julie | 4031 - SALES | Regular Full Time | Regional Sales Manager |
| Rane | Blake | 4031 - SALES | Regular Full Time | Regional Sales Manager |
| Thompson | Heath | 4042 - Strategic Accounts & Contracting | Regular Full Time | Senior Director of Strategic Accounts, Americas |
| Bohlen | Renee | 4042 - Strategic Accounts & Contracting | Regular Full Time | Senior Manager, Contracts |
| Brown-Johnson | Kymm | 1002 - FINANCE | Regular Full Time | Contractor |
| Shuster | Phil | 4031 - SALES | Regular Full Time | Regional Sales Manager |
| Ulrich | Steven | EMEA Sales | Regular Full Time | Senior Director of Strategy & Analytics |
| Jackson | Lindsay | 4031 - SALES | Regular Full Time | Regional Sales Manager |
| Green | April | 4031 - SALES | Regular Full Time | Senior Executive Assistant |
| Lakstins | Katie | 4045 - Medical Affairs & Education | Regular Full Time | Senior Medical Science Liaison |
| Guarino | Vincent | 4031 - SALES | Regular Full Time | Director, Distributor Development |
| Voytovich | Will | 1002 - FINANCE | Regular Full Time | Senior Financial Analyst |
| Caputo | Marissa | 1001 - ADMIN | Regular Full Time | Director of Global Medical Education Strategy & Pr |
| Godel | Aaron | 4042 - Strategic Accounts & Contracting | Regular Full Time | Strategic Accounts Manager |
| Clare | Jason | 3023 - MAN | Regular Full Time | Manufacturing Technician II |
| O'Shaughnessy | Nora | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Direct Sales Representative |
| Sanchez | Jessica | 3022 - LOG | Regular Full Time | Safety Specialist |
| Kramer | Kyle | 3023 - MAN | Regular Full Time | Manufacturing Technician II |
| Aulby | Emily | 2012 - QA | Regular Full Time | Supplier Quality Engineer |
| Victor | Tony | 1002 - FINANCE | Regular Full Time | Financial Analyst |
| Pullen | Matthew | 4031 - SALES | Regular Full Time | Regional Sales Manager |
| Bradley | Jay | 4031 - SALES | Regular Full Time | Sr Manager of Sales Training & Education |
| Dupre | Dickie | 4031 - SALES | Regular Full Time | Regional Sales Manager |
| Jackson | Robert | 1002 - FINANCE | Regular Full Time | Credit & Collections Manager |
| Juarez-Rincon | Antoinette | 3023 - MAN | Regular Full Time | Manufacturing Technician II |
| Villa | Beth | 2012 - QA | Regular Full Time | Quality Control Associate Scientist |
| Kuhlmann | Nadia | 3021 - CUSTSRVC | Regular Full Time | Commercial Operations Manager- Billing |
| Garcia | Patrick | 3021 - CUSTSRVC | Regular Full Time | Field Inventory Auditor |
| Roberts | Wes | 4031 - SALES | Regular Full Time | Regional Sales Manager |
| Harlan | Jason | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Direct Sales Representative |
| Iturbe | Iker | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Direct Sales Representative |
| Delor | Jim | 4031 - SALES | Regular Full Time | VP, Sales Education & Development, General Manager |
| Hays | Lori | 4041 - Global Regulatory | Regular Full Time | VP of Regulatory |
| Geier | Sean | 1002 - FINANCE | Regular Full Time | Senior Accountant |
| Ayllon | Luis | 4040 - Global Innovation | Regular Full Time | Sr Director of Product Innovation |
| Loye | Mary | 3021 - CUSTSRVC | Regular Full Time | Customer Service Analyst |
| Temperato | Lori | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Direct Sales Representative |
| Kurcz | Bryan | 4031 - SALES | Regular Full Time | Regional Sales Manager |
| Burke | Kimberly | 1001 - ADMIN | Regular Full Time | General Counsel |
| Clay | Joey | 3021 - CUSTSRVC | Regular Full Time | Customer Service Analyst |
| Camano | Javier | 4040 - Global Innovation | Regular Full Time | Director, Global Innovation |
| Lynch | Nicole | 4045 - Medical Affairs & Education | Regular Full Time | Event Specialist |
| Schelble | Kim | 4038 - Global Marketing | Regular Full Time | Vice President Strategy, Marketing and Analytics |
| Pahls | Tony | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Direct Sales Representative |
| Shirley | John | 1002 - FINANCE | Regular Full Time | Senior Financial Analyst |
| Luster | Tim | 3021 - CUSTSRVC | Regular Full Time | Field Inventory Auditor |
| Isaias | Anacleto | 4038 - Global Marketing | Regular Full Time | Business Intelligence Manager |
| Korte | Lacy | 4031 - SALES | Regular Full Time | Regional Sales Manager |
| Bange | Ashley | 3021 - CUSTSRVC | Regular Full Time | Commercial Operations Support Analyst |
| Johnson | Scott | 4035 - Clinical Education | Regular Full Time | I-Senior Director of Clinical Affairs |
| Geiger | Stephanie | 1001 - ADMIN | Regular Full Time | Office Manager |
| Schwartz | Lauren | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Market Development Specialist |
| Schoen | Alex | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Direct Sales Representative |
| Guarino | Vinny | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Direct Sales Representative |
| Buckles | Julie | 1002 - FINANCE | Regular Full Time | Accounting Manager |
| Ake | Philip | 1001 - ADMIN | Regular Full Time | Senior Director - Global Program Management |
| Jancovic | Michael | 4031 - SALES | Regular Full Time | Regional Sales Manager |
| Martinez | John | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Direct Sales Representative |

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|---|---|---|---|---|
| Weaver | Caryn | 1001 - ADMIN | Regular Full Time | Senior Manager, People Business Partner |
| Winfrey | Nicholas | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Direct Sales Representative |
| Witt | Molly | 4045 - Medical Affairs & Education | Regular Full Time | Sr. Administrative Assistant |
| Kuntz | James | 4031 - SALES | Regular Full Time | Regional Sales Manager |
| Kameron | Nicholas | 1002 - FINANCE | Regular Full Time | Director, IT |
| Toutant | Kristen | 4038 - Global Marketing | Regular Full Time | Director, Global Strategy & Upstream Marketing |
| Mattorano | Devin | 3022 - LOG | Regular Full Time | Distribution Specialist |
| Ollin | Kat | 1001 - ADMIN | Regular Full Time | Manager - Talent Acquisition |
| LO | Deesle | 3023 - MAN | Regular Full Time | Manufacturing Technician 1 |
| McConnell | Garland | 3023 - MAN | Regular Full Time | Manufacturing Technician II |
| Shah | Manisha | 4041 - Global Regulatory | Regular Full Time | Senior Manager Of Regulatory Affairs |
| Homolka | Denise | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Direct Sales Representative |
| Price | Keith | 4038 - Global Marketing | Regular Full Time | Director, Product Management (P15 & Matrix) |
| Daigle | Laura | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Direct Sales Representative |
| Donor | Ed | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Direct Sales Representative |
| Bansal | Ajay | 1002 - FINANCE | Regular Full Time | Chief Financial Officer |
| Barton | Roezina | 4042 - Strategic Accounts & Contracting | Regular Full Time | Director, Global Contracts & Commercial Excellence |
| TERRY | CAMILLE | 1003 - FAC | Regular Full Time | Engineering & Maintenance Activities Coordinator |
| Sipe | Alison | 4038 - Global Marketing | Regular Full Time | Reimbursement Manager |
| Parker | Rachel | 3021 - CUSTSRVC | Regular Full Time | Field Inventory Lead |
| Cook | Delia | 4038 - Global Marketing | Regular Full Time | Sr. Director, Marketing Communications |
| Shacklette | Meagan | 1002 - FINANCE | Regular Full Time | Sr. Accounts Payable Specialist |
| Skinner | Johnny | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Direct Sales Representative |
| Jefferson | Stewart | 4038 - Global Marketing | Regular Full Time | I-CANAM General Manager |
| Dancose | Frederic | 4038 - Global Marketing | Regular Full Time | I-Factor Product Specialist |
| Thompson | Tracey | 4031 - SALES | Regular Full Time | I-UK Country Manager |
| Sommer | Noemie | 4031 - SALES | Regular Full Time | I-UK Product Specialist |
| Addison | Jessica | 4035 - Clinical Education | Regular Full Time | I-International Marketing Manager |
| Mays | Rachel | 4035 - Clinical Education | Regular Full Time | I-Clinical Research Manager |
| Peters | Alison | 4038 - Global Marketing | Regular Full Time | International |
| Sivshankar | Shankar | 4035 - Clinical Education | Regular Full Time | I-Director of Clinical Operations |
| Miller | Michael | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Direct Sales Representative |
| Ashcroft | George | 1002 - FINANCE | Regular Full Time | Senior Financial Analyst |
| Schroeder | Valeska | 1001 - ADMIN | Regular Full Time | Chief Executive Officer |
| McMahon | John | 4031 - SALES | Regular Full Time | Sr Sales Operations Specialist |
| Franco Aguilar | Nadia | 3023 - MAN | Regular Full Time | Manufacturing Technician 1 |
| Thompson | Sean | 4031 - SALES | Regular Full Time | Regional Sales Manager |
| Espinosa | John | 1003 - FAC | Regular Full Time | Maintenance Manager |
| Bereza | Jazz | 3022 - LOG | Regular Full Time | Distribution Specialist |
| Freeman | Bobby | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Market Development Specialist |
| Wright | Justin | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Market Development Specialist |
| Mouse | Mickey | 1001 - ADMIN | Regular Full Time | |
| Belle | Tinker | 1001 - ADMIN | Regular Full Time | |
| Cherf | John | 4045 - Medical Affairs & Education | Regular Full Time | Chief Medical Officer |
| Raptis | Josh | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Direct Sales Representative |
| Harrold | Dan | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Direct Sales Representative |
| Coburn | Clint | 2012 - QA | Regular Full Time | Quality Control Associate Scientist |
| Frankhouser | Syd | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Market Development Specialist |
| Allen | Libbie | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Market Development Specialist |
| Powers | Angie | 1001 - ADMIN | Regular Full Time | Manager, Payroll & Benefits |
| Oliphant | Duncan | 4031 - SALES | Regular Full Time | Regional Sales Manager |
| Herrema | Blake | 2013 - RD | Regular Full Time | Product Development Engineer |
| Murphy | Brian | 4031 - SALES | Regular Full Time | Regional Sales Manager |
| Thai | Lauren | 1001 - ADMIN | Regular Full Time | Compliance Officer |
| Benoit-Ledoux | Tim | 1001 - ADMIN | Regular Full Time | Associate General Counsel |
| KLEMM | PETER | 4031 - SALES | Regular Full Time | Regional Sales Manager |
| Johnson | David | 1002 - FINANCE | Regular Full Time | IT Endpoint Engineer |
| Padavano | Nick | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Direct Sales Representative |
| Winslow | Nicole | 4034 - MARK | Regular Full Time | Event Specialist |
| Balsley | Pam | 4034 - MARK | Regular Full Time | Event Specialist |
| Erickson | Samuel | 1003 - FAC | Regular Full Time | Maintenance Tech III |
| Nevarez | Lupe | 3023 - MAN | Regular Full Time | Manufacturing Technician I |
| Bonin | Bridget | 1002 - FINANCE | Regular Full Time | IT Endpoint Engineer |
| Lombardi | Lucian | 1002 - FINANCE | Regular Full Time | Staff Accountant |
| Alford | Glen | 3023 - MAN | Regular Full Time | Manufacturing Lead |
| Anderson | Tom | 4031 - SALES | Regular Full Time | Area Vice President |
| August | Gussie | 4031 - SALES | Regular Full Time | Regional Sales Manager |
| Littleford | Chris | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Direct Sales Representative |
| Gopal | Mani | 1001 - ADMIN | Regular Full Time | Chief Operating Officer |
| Laster | Monique | 4042 - Strategic Accounts & Contracting | Regular Full Time | Strategic Accounts Manager |
| McLeod | Timothy | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Direct Sales Representative |
| Brown | Mickey | 4038 - Global Marketing | Regular Full Time | VP, Access & Reimbursement |
| Hernandez | Catrina | 3023 - MAN | Regular Full Time | Manufacturing Technician I |
| Goetze | Grant | 4038 - Global Marketing | Regular Full Time | Global i-Factor Product Manager |
| Kindsfather | Brian | 4031 - SALES | Regular Full Time | Regional Sales Manager |

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|---|---|---|---|---|
| Kafel | Maura | 4042 - Strategic Accounts & Contracting | Regular Full Time | Contract Manager |
| Saenz | Carlos | 1002 - FINANCE | Regular Full Time | IT, Systems Administrator |
| Pocock | Jared | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Direct Sales Representative |
| Rhodes | Megan | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Direct Sales Representative |
| Jackson | Greg | 4042 - Strategic Accounts & Contracting | Regular Full Time | Senior Director of Strategic Accounts, Americas |
| Muell | Leah | 4031 - SALES | Regular Full Time | Sales Training Manager- Commercial Education & Dev |
| Hinz | Emily | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Associate Sales Representative |
| Miller | Patrick | 4042 - Strategic Accounts & Contracting | Regular Full Time | Dir, Enterprise Applications (SAP) |
| Evans | Veronica | 1002 - FINANCE | Regular Full Time | Payment Application Specialist |
| Truman | Avery | 1001 - ADMIN | Regular Full Time | Office Assistant / Event Coordinator |
| KELLY | Brian | 4031 - SALES | Regular Full Time | Regional Sales Manager |
| Mehdi | Omar | 4031 - SALES | Regular Full Time | Senior Regional Sales Manager |
| Flynn | Bob | 4031 - SALES | Regular Full Time | Area Vice President |
| Buell | Kaytie | 1002 - FINANCE | Regular Full Time | Senior Accountant |
| Curry | Michael | 3022 - LOG | Regular Full Time | Receiving & Returns Specialist 2 |
| Lopez | Donald | 3023 - MAN | Regular Full Time | Manufacturing Technician IV |
| NOHAVEC | DONALD | 1001 - ADMIN | Regular Full Time | Project Manager |
| Biernat | Joe | 4030- DSR/MDS US Sales Direct SalesDist | Regular Full Time | Direct Sales Representative |
| Aliyu | Avosuahi | 1002 - FINANCE | Regular Full Time | Assistant Controller |
| VANCE | JOSEF | 4031 - SALES | Regular Full Time | VP, Sales Operations & Training |
| Huntington | ROBIN | 3023 - MAN | Regular Full Time | Manufacturing Supervisor |
| JANSEN | Todd | 4031 - SALES | Regular Full Time | Senior Regional Sales Manager |
| Milton | Johan | 1003 - FAC | Regular Full Time | Validation Engineer Manager |
| NARDI | THOMAS | 1002 - FINANCE | Regular Full Time | Senior Director Of Finance And It Systems |
| O'CONNOR | PATRICK | 4040 - Global Innovation | Regular Full Time | Vice President Of Clinical And Market Development |
| Vang | Kelly | 3023 - MAN | Regular Full Time | Manufacturing Tech III |
| Hawkins | Pairis | 3023 - MAN | Regular Full Time | Manufacturing Technician III |
| Ellis | Stephanie | 3022 - LOG | Regular Full Time | Safety Coordinator |
| Martz | Hilarie | 4031 - SALES | Regular Full Time | Regional Sales Manager |
| WELLS | CHRISTOPHER | 3023 - MAN | Regular Full Time | Senior Manager, Manufacturing |
| Radomile | Caleb | 2013 - RD | Regular Full Time | R & D Scientist |
| Cheves | Michael | 3023 - MAN | Regular Full Time | Manufacturing Supervisor |
| WILDER | COURTNEY | 4031 - SALES | Regular Full Time | Senior Regional Sales Manager |
| VESSELS | MAX | 3022 - LOG | Regular Full Time | Specialist 3, Distribution |
| Sutton | Katherine | 1002 - FINANCE | Regular Full Time | Collections Specialist |
| SMITH | BRIENNE | 4031 - SALES | Regular Full Time | Regional Sales Manager |
| Enna | Genevra | 1002 - FINANCE | Regular Full Time | Vice President, Controller |
| Smith | Holly | 3023 - MAN | Regular Full Time | Vice President, Operations |
| THOMPSON | TC | 1003 - FAC | Regular Full Time | Director, Facilities & Engineering |
| Christianson | Sara | 2012 - QA | Regular Full Time | Senior Qc Scientist |
| Friedli | Jason | 3023 - MAN | Regular Full Time | Manufacturing Technician Iii |
| Henderson | Hannah | 3021 - CUSTSRVC | Regular Full Time | Customer Service Analyst Ii |
| SZASZ | CSABA | 1003 - FAC | Regular Full Time | Supervisor, Engineering/Projects |
| Cross | Jeanie | 3023 - MAN | Regular Full Time | Materials Manager |
| LOVULLO | MICHAEL | 4038 - Global Marketing | Regular Full Time | MarComm Manager |
| Gantt | Jolie | 3021 - CUSTSRVC | Regular Full Time | Field Inventory Lead |
| Corneliussen | Garrett | 1002 - FINANCE | Regular Full Time | Manager, Finance |
| LAPLANT | Roxanne | 4042 - Strategic Accounts & Contracting | Regular Full Time | Mo-executive Administrative Assistant |
| Beadles | Joshua | 3023 - MAN | Regular Full Time | Manufacturing Technician IV |
| HUERTA | DANIEL | 1003 - FAC | Regular Full Time | Maintenence Tech IV |
| PEARSON-BAIRD | Krista | 4034 - MARK | Regular Full Time | Customer Engagement And Initiatives Manager |
| SHEARER | EMMETT | 4045 - Medical Affairs & Education | Regular Full Time | Senior Manager Of Clinical Research |
| Bell | Jason | 1002 - FINANCE | Regular Full Time | Sr Accounts Receivable Specialist |
| SHEK | ROBERT | 4031 - SALES | Regular Full Time | Area Director |
| YEAROUS | SHARI | 3021 - CUSTSRVC | Regular Full Time | Customer Service Analyst |
| Coniglio | Taylor | 1001 - ADMIN | Regular Full Time | Senior Office Admin |
| HORNBERGER | MELISSA | 4031 - SALES | Regular Full Time | Senior Regional Sales Manager |
| Davis | Katherine | 2013 - RD | Regular Full Time | Senior Director, Research & Development |
| Bonicelli | Michael | 1002 - FINANCE | Regular Full Time | Financial Analytics & Business Intelligence MGR |
| Bohrman | Patrick | 4031 - SALES | Regular Full Time | Dir, US Sales Operations |
| Cox | William | 4031 - SALES | Regular Full Time | Regional Sales Manager |
| Barnes | Tristan | 2013 - RD | Regular Full Time | Principal Scientist |
| Golliday | Aaron | 4031 - SALES | Regular Full Time | Area Director |
| Greicius | Greg | 4031 - SALES | Regular Full Time | Senior Regional Sales Manager |
| LESAGE | SEAN | 4031 - SALES | Regular Full Time | Area Vice President |
| Hannigan | Nolan | 2013 - RD | Regular Full Time | Principal Engineer |
| Grush | Rachael | 3022 - LOG | Regular Full Time | Receiving & Returns Specialist |
| Austin | Kathleen | 4038 - Global Marketing | Regular Full Time | Sr Global Product Manager |
| Destefano | Frank | 4031 - SALES | Regular Full Time | Area Vice President |
| Sears | Ronnie | 3022 - LOG | Regular Full Time | Warehouse Supervisor |
| Rodriguez | Stephanie | 3021 - CUSTSRVC | Regular Full Time | CS Project Lead |
| REECE | Matt | 3022 - LOG | Regular Full Time | Director, Logistics & Safety |
| VERA | CATHERINE | 3023 - MAN | Regular Full Time | PurchasingAgent |
| Le | Thao | 2012 - QA | Regular Full Time | Sr. QC Scientist |
| Sorensen | Maria | 1001 - ADMIN | Regular Full Time | Manager, People & Office Services |

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|---|---|---|---|---|
| ROCKWELL | ADAM | 2012 - QA | Regular Full Time | Sr. Quality Engineer |
| Johnson | Brice | 1001 - ADMIN | Regular Full Time | VP, People |
| MCCOMIS | ALANYA | 1001 - ADMIN | Regular Full Time | Director, People Operations |
| Edwards | Waylon | 4031 - SALES | Regular Full Time | Senior Regional Sales Manager |
| MURPHY | SEAN | 4031 - SALES | Regular Full Time | Senior Regional Sales Manager |
| Thomas | Matthew | 4031 - SALES | Regular Full Time | Chief Commercial Officer |
| MARX | JEFF | 1001 - ADMIN | Regular Full Time | Chief Scientific Officer |
| Hernandez | Daniel | 1003 - FAC | Regular Full Time | Maintenance Tech Iii |
| Zepeda | Lupita | 3022 - LOG | Regular Full Time | Logistics CS Backflow Coordinator |
| Fleming | Isaiah | 3022 - LOG | Regular Full Time | International Distribution Coordinator |
| Nauman | Jonathan | 1003 - FAC | Regular Full Time | Jr Validation Engineer |
| Alizada | Mehdi | 2012 - QA | Regular Full Time | Sr. Quality Engineer |
| WHITE | Roger | 2011 - CLIN | Regular Full Time | Vice President Of Regulatory |
| Hanson | Cody | 2012 - QA | Regular Full Time | Director of Quality |
| Kudrna | ERIN | 1001 - ADMIN | Regular Full Time | Office Assistant Ii |
| Connor | Jerome | 2013 - RD | Regular Full Time | Vice President Of Research And Developement |
| Homewood | Jennah | 3021 - CUSTSRVC | Regular Full Time | Lead Mobile App Manager |
| Tillery | Shawn | 2012 - QA | Regular Full Time | Document Control/training Coordinator |
| Cook | Joshua | 4031 - SALES | Regular Full Time | Regional Sales Manager |
| PREUSSE | Rick | 4031 - SALES | Regular Full Time | Sr Director, Sales Education & Training |

| Contracted HCPs |
| --- |
| Aksu Kenan |
| Ament Jared |
| Arndt Stephen |
| Bailey Greg |
| Bryan Bean |
| Burke James |
| Brusovanik Georgiy |
| Cannestra Andrew |
| Casper David |
| Chaput Christopher |
| Chen Dan T (Tan) |
| Chen Thomas |
| Kim Choll |
| Cohen Timothy |
| DelSole Edward |
| Robert Floros |
| Girasole Gerard |
| Glazer Paul |
| Hah Ray |
| Kazemi Noojan |
| Khan Safdar |
| Lane Joseph |
| Lau Darryl |
| Loidolt Travis |
| O'Toole John |
| McConnel Jeffrey |
| Michaud Marc |
| Morreale Joseph |
| Passias Peterson |
| Rajpal Sharad |
| Patel Amit |
| Reid Patrick |
| Sebastian Arjun |
| Shamie Nick |
| Shimer Adam |
| Soondar Steve |
| Steinmetz Michael |
| Than Khoi |
| Tsen Andrew |
| Verdolin Michael |
| Wright Neill |
| Smith Justin |
| Jain Deeptee |
| Czyz Marcin |
| Bess, Robery Shay |
| Theodore Nicholas |
| Cheng Boyle |

| Vendors in Open Pos | |
|---|---|
| Vendor BP # in Old system | Vendor Name |
| 5468 | Technipaq |
| 5056 | Bachem Americas, Inc. |
| 5972 | CPCneutek |
| 5381 | Plas-Tech Engineering, Inc |
| 5797 | DSM Biomedical |
| 5352 | IMCD US, LLC |
| 5518 | VWR International |
| 5066 | Biologos, Inc. |
| 5075 | BPO Parts |
| 5848 | Merit Press |
| 5723 | Bergdahl Associates, Inc |
| 5443 | SP Scientific |
| 5184 | Fisher Scientific |
| 5115 | Colorado BioScience Assn |
| 5743 | CDW Direct |
| 5223 | Hazen Research, Inc. |
| 5334 | Nelson Laboratories |
| 6336 | Golden Security |
| 5518 | VWR International |
| 5629 | Transcat, Inc. |
| 5494 | ULINE |
| 6070 | Healthcare Medical Waste Services, |
| 5595 | Copyright Clearance Center, INC. |
| 5296 | McMaster-Carr Supply Co. |
| 5457 | Dell Financial Services LLC |
| 6219 | Rexel USA, Inc. |
| 6520 | Advanced Technology Consulting Serv |
| 6382 | Webster Associates, Inc. |
| 5630 | DO NOT USE |
| 5194 | General Air |
| 5133 | Avvale, Inc. |
| 5688 | A Peace of Work/ Jayme Price Consu |
| 5491 | Qunique GmbH |
| 6330 | Plante & Moran, LLC |
| 5703 | Ocean Star Audit Services |
| 5567 | Continental Clay Company |
| 5607 | Thomas Scientifc, LLC Co. |
| 5774 | Kimberly Brown-Johnson |
| 5749 | Ashley Nikki Barnes |
| 5823 | Realists Training Technologies GmbH |
| 5233 | Infinity Labs |
| 5420 | Integrated Document Technologies |
| 5285 | ProExhibits |
| 5597 | DH Pace Door Services |
| 5331 | NAMSA |

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|---|---|
| 5103 | Cintas First Aid & Safety |
| 5604 | Gartner Inc |
| 7136 | Red Bigfoot, LLC |
| 5625 | Talosix LLC |
| 5042 | Rush University Medical Center |
| 5404 | University of Cincinnati Physicians |
| 5327 | UT Health San Antonio |
| 6355 | Indiana Spine Group, P.C. |
| 9045 | Thomas Jefferson University- CLINIC |
| 7129 | The Orthopaedic Research Foundation |
| 5054 | Cleveland Clinic Health System |
| 5214 | Saint Francis Hospital & Medical Ce |
| 5504 | University of Virginia |
| 5252 | University of Alabama at Birmingham |
| 9028 | Northwestern University |
| 5098 | Swedish Health Services |
| 5209 | Scientific Education & Research |
| 5180 | Cedars Sinai Medical Center |
| 5202 | University of South Florida |
| 5204 | Grainger |
| 6159 | LabConnect, LLC |
| 5170 | Ernst & Young LLP |
| 5435 | FP Mailing Solutions |
| 5253 | Orthopaedic Institute of |
| 5142 | The Research Foundation |
| 5400 | Regents of the University |
| 5817 | Mobas |
| 7135 | BP MEDICAL LLC |
| 6312 | Duke University |
| 5305 | The Research Foundation for |
| 6309 | Carle Foundation Hospital |
| 6179 | Mapi Research Trust |
| 5201 | TBI Clinical Research, LLC |
| 5680 | CDesigns LLC |
| 5534 | Resa Service, LLC |
| 5468 | Technipaq |
| 5171 | Eurofins EAG Materials Science, LLC |
| 5430 | Summit Search Consultants LLC |
| 6263 | Automation Direct |
| 5948 | Remedy Medical, LLC |
| 5664 | Jeffrey Tyber |
| 5985 | Pangea West Incorporated |
| 5699 | AKRA TEAM GmbH |
| 5217 | Emergo Global Representation, LLC |
| 5071 | STERIS Corporation |
| 6040 | Zilligent, LLC |
| 5793 | Darryl Lau |

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|---|---|
| 5161 | Electro-Steam Generator Corporation |
| 5856 | Buhlmann Diagnostics Corp. |
| 6047 | Scientific Global Communications, I |
| 6056 | Concentric Partners, LLC |
| 5708 | QUNIQUE GmbH-Germany |
| 5123 | Condit Exhibits, LLC |
| 5268 | Kragh Information Technology |
| 5657 | J2T Recruiting Consultants, Inc. |
| 5114 | Magnifi Group, Inc. |
| 6184 | The Curry Rockefeller Group, LLC |
| 5512 | People 2.0 North America, LLC |
| 6208 | AVI-SPL LLC |
| 5135 | Oliver Healthcare Packaging Company |
| 5109 | Zoho Corporation |
| 5381 | Plas-Tech Engineering, Inc |
| 6270 | Tina Aspinall |
| 6353 | Allegheny General Hospital |
| 5931 | McGill University Health Centre |
| 5928 | Unity Health Toronto |
| 5685 | University of Calgary |
| 6054 | University of Manitoba |
| 5436 | Evoqua Water Technologies LLC |
| 6279 | London Health Sciences Centre Resea |
| 6281 | Veeva Systems Inc. |
| 6280 | Centre De Recherche Chum |
| 5191 | Experis US, Inc. |
| 5968 | Linkedin Corp |
| 6290 | Accely Inc |
| 6237 | SAP America, Inc. |
| 6294 | Grant Goetze |
| 6293 | Falkor Digital |
| 5117 | Colorado State University |
| 6273 | Sarah Ramsay |
| 6122 | Sygehus Lillebaelt |
| 6408 | Dana Mead |
| 5880 | Millennium Research Group, Inc. |
| 5633 | We Know Data |
| 6380 | Kastle Systems of Texas, LLC |
| 6265 | JW Marriott Camelback Inn |
| 5150 | Sound Advice Consulting Services, L |
| 6419 | ENCORE GROUP (USA) LLC |
| 6376 | RazorEdge Technologies, L.L.C. |
| 6437 | CVENT, Inc. |
| 5203 | HubSpot, Inc. |
| 6172 | Mortar Advertising, Inc. |
| 5992 | Equitas Life Sciences, LLC |
| 5797 | DSM Biomedical |

| | |
|---|---|
| 5607 | NCI, a Thomas Scientifc, LLC Co. |
| 5689 | ZS Associates, Inc. |
| 5663 | Global Healthcare Exchange (GHX) |
| 6218 | Esker, Inc. |
| 5112 | Stratus Building Solutions |
| 6305 | Specialty Incentives, Inc. |
| 5133 | NIMBL Worldwide, Inc. |
| 6015 | MedPro System LLC |
| 5342 | CFGI, LLC |
| 6223 | KPMG LLP |
| 5674 | Gilmartin Group LLC |
| 6058 | Meriplex Communications, LTD |
| 6086 | RapidScale Inc. |
| 5725 | KnowBe4 Inc. |
| 5490 | Heart+Mind Strategies |
| 6352 | Aerotek, Inc. |
| 5050 | Ashley's Electric, LLC |
| 5838 | Healthlink International |
| 5315 | SpinePassBook, LLC |
| 5949 | Biomedical Statistical Consulting |
| 5837 | Emergent Clinical Consulting, LLC |
| 6114 | Foundation for Orthopaedic Research |
| 5765 | Justin Smith, MD, PhD |
| 5272 | Kelly Anne Enterprises, LLC |
| 5303 | Medical Metrics, Inc. |
| 5096 | Icahn School of Medicine at Mount S |
| 6240 | Norton Healthcare, Inc. |
| 7108 | PAS Consulting |
| 5282 | Regents of the UC Irvine |
| 5196 | Regents of the University of Michig |
| 9060 | Rothman Institute - FOR CLINICAL TR |
| 6075 | Statistics & Data Corporation |
| 6060 | University of Connecticut Health Ce |
| 5527 | Western IRB |
| 6036 | Hogan Lovells International LLP |
| 6423 | UNIVERSITY OF PITTSBURGH |
| 6521 | University of Pittsburgh Physicians |
| 6197 | Ortho Consulting Group Ltd |
| 6448 | Core 82 Inc |
| 6451 | Mani Gopal |
| 6261 | Terryberry Company LLC |
| 5215 | HealthLink Europe BV |
| 5271 | Raylytic GmbH |
| 5624 | Rigshospitalet |
| 6203 | Axiom Global Inc |
| 6452 | Saunders & Silverstein LLP |
| 6463 | David Wingate, LLC |

| | |
|---|---|
| 6522 | Vendormate, Incorporated |
| 5848 | Merit Press |
| 5723 | Bergdahl Associates, Inc |
| 6024 | HR Clark & Associates LLC |
| 5016 | Adstick Custom Labels |
| 5028 | All Packaging Company |
| 5809 | RRY Publications, LLC |
| 5529 | Wolters Kluwer Health, Inc. |
| 5164 | Elsevier |
| 5082 | BSI America |
| 5816 | Art IQ, LTD |
| 6475 | Western Kentucky Spine Research, LL |
| 6479 | RMT Equipment Leasing, LLC |
| 6165 | TLD Solutions LLC |
| 6236 | Ideal Vacuum Products LLC |
| 6480 | Ten Bridge Communications, Inc. |
| 6128 | Concur Technologies, Inc. |
| 5438 | Sigma Aldrich |
| 6524 | IN-X Machine Inc. |
| 6472 | Collagen Solutions, Asia Pacific Re |
| 6323 | Joint Biomedical & Biomaterials |
| 5474 | Boulder Biomed LLC |
| 6492 | Erika Iverson Palmer |
| 6487 | Meredith Morin Graphic Design |
| 6494 | Biopolicy Innovations LLC |
| 5238 | Life Technologies |
| 5219 | Miller A. Montealegre |
| 5918 | Keep International S.r.l. |
| 6283 | American Medical Regulatory Associa |
| 6537 | Collagen Solutions US, LLC |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -- WO66-G609
Silver Spring, MD 20993-0002

November 3, 2015

Cerapedics, Incorporated
Mr. Roger N. White
Clinical and Regulatory Affairs
11025 Dover Street Suite 1600
Westminster, Colorado 80021

Re: P140019
i-FACTOR™ Peptide Enhanced Bone Graft
Filed: August 27, 2014
Amended: February 13, May 20, and June 9, 2015
Procode: NOX

Dear Mr. White:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the i-FACTOR™ Peptide Enhanced Bone Graft. This combination product is indicated for use in skeletally mature patients for reconstruction of a degenerated cervical disc at one level from C3-C4 to C6-C7 following single-level discectomy for intractable radiculopathy (arm pain and/or a neurological deficit), with or without neck pain, or myelopathy due to a single-level abnormality localized to the disc space, and corresponding to at least one of the following conditions confirmed by radiographic imaging (CT, MRI, X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels, after failure of at least 6 weeks of conservative treatment. i-FACTOR™ Peptide Enhanced Bone Graft P-15 Putty must be used inside an allograft bone ring and with supplemental anterior plate fixation. We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at 3 years. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

Continued approval of this PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. Two copies of this report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84. This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final UDI rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. For more information on these requirements, please see the UDI website, http://www.fda.gov/udi.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

You have agreed to the following product stability requirements with the reports submitted separately from the annual reporting requirement:

1. Conduct bioactivity stability test for the first 3 production batches of i-FACTOR™ Peptide Enhanced Bone Graft product manufactured and packaged according to the commercialized manufacturing process. The stability study should be performed at the long term controlled storage condition of 25°C/60%RH with test frequency of 0, 6, 12 months for the 1st year, every 6 months for the 2nd year and annually thereafter through the shelf life. The stability data report should be submitted as a "Report – Other" due at the same time as the annual report, but submitted separately from the annual report.

2. Place a minimum one commercial batch of the finished product into long-term stability testing at 25°C/60% RH through the shelf life on an annual basis if manufactured.

3. Withdraw from the market, any batches that fail to meet the approved specifications for the putty product during long-term stability evaluations.

In addition to the Annual Report requirements, you must provide the following data in post-approval study (PAS) reports for each PAS listed below. Separate PAS Progress Reports must be submitted for each study every six (6) months during the first two (2) years of the study and annually thereafter, unless otherwise specified by FDA. Two (2) copies of each report, identified

as an "ODE Lead PMA Post-Approval Study Report" in accordance with how the study is identified below and bearing the applicable PMA reference number, should be submitted to the address below.

ODE Lead PMA Post-Approval Study – i-FACTOR™ Peptide Enhanced Bone Graft Continuation Study: The Office of Device Evaluation (ODE) will have the lead for this clinical study, which was initiated prior to device approval. The i-FACTOR™ Peptide Enhanced Bone Graft Continuation Study is a continuation of the collection of data from subjects who were enrolled in the clinical study used to support approval of the PMA. The purpose of the study is to collect longer-term data describing the safety and effectiveness of the identified product. The clinical and radiographic endpoints identified in the original protocol (included in Attachment IV-4.6 of the original PMA submission) will continue to be collected annually until each subject has had a total of six years' worth of data collected.

It is expected that 220 total subjects will be enrolled in the study. A conservative estimate of expected number of subjects at 6 years follow-up is 170 subjects (*i.e.* loss of 10 subjects per year due to withdrawals, death and other causes). Further, a follow-up rate of up to 70% is expected at all follow-ups. Thus, data from a total of 154 subjects are expected to be available at year 3 and from 120 subjects at year 6.

The working study hypothesis is that i-FACTOR™ Peptide Enhanced Bone Graft will be non-inferior to autologous bone. This working hypothesis will be tested by a non-inferiority approach as follows. In order to be a success, non-inferiority structured H0 for each primary efficacy endpoint has to be rejected. Three independent hypotheses will be tested, for each of the primary endpoints using the same non-inferiority margins as in the main study. The hypotheses will be tested with one-sided and two-sided 95% C.I. For the fusion and neurological success primary endpoints, the exact binomial confidence interval will be created. For the change in NDI primary endpoint, the confidence intervals for the differences in mean change between the groups adjusting for baseline NDI value will be created. If the confidence interval does not include non-inferiority margin, the H0 will be rejected. An evaluation for the need to adjust the analysis for possible differences between the groups will be included.

Statistical power:

- It is estimated that the fusion rate will be between 98% and 100% at all follow-ups based on the main study results. At 3 years, the study will have 99% power and at 6 years it will have 98% power to reject non-inferiority H0 with non-inferiority margin of 10%.

- The study will have 97% power at 3 years and 93% power at 6 years to reject H0 for the change in NDI outcome under the standard deviation assumption of 19 (based on the main study) and a non-inferiority margin of 11.

- The study will have 95% power at 3 years and 90% power at 6 years to reject non-inferiority H0 for neurological success outcome under the assumption of a neurological success rate of 93% as observed in the main study and a non- inferiority margin of 15%.

The rate of adverse events will be compared between the i-FACTOR™ Peptide Enhanced Bone Graft and the control arm using the Fisher exact test and superiority approach, in the same way as in the original IDE study. Failure to reject H0 or, rejection of H0 in favor of i-FACTOR™ Peptide Enhanced Bone Graft group will meet safety success. The rate of subsequent surgical interventions at the index level will also be compared.

The data from this study will be submitted as part of the annual report and will include the following data collected annually for each subject:

1. a description of any surgical interventions, which will include reoperations, removals, revisions, and supplemental fixations;

2. a radiographic assessment of fusion using the same criteria employed in the original IDE study;

3. an assessment of neurological outcomes;

4. an assessment of pain and function using the same criteria employed in the original IDE study (*i.e.*, change in NDI and change in neck and arm VAS for pain); and

5. other primary and secondary endpoints not specified in items 1-3 above, as specified in the IDE study protocol addendum.

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA. In addition, the results from any post approval study should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of a PMA Supplement. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm).

Within 30 days of your receipt of this letter, you must submit a PMA supplement that includes a complete protocol of your post-approval study described above. Your PMA supplement should be clearly labeled as an "ODE Lead" as noted above and submitted in triplicate to the address below. Please reference the PMA number above to facilitate processing. If there are multiple

protocols being finalized after PMA approval, please submit each protocol as a separate PMA supplement.

Before making any change affecting the safety or effectiveness of the device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" (www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm).

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

In accordance with the recall requirements specified in 21 CFR 806.10, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket

number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. Final printed labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in 6 copies, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
PMA Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Aric Kaiser at 301-796-6425 or aric.kaiser@fda.hhs.gov.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Division Director
Division of Orthopaedic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

# 4G

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

**Non-Refundable $1,000 Fee**

Rev (08/17/2022)

| Where is the facility located? | | ☐ Nevada ■ Out-of-State |
|---|---|---|
| **Type of Application (check applicable box)** | | **Wholesaler Business Type (check applicable box)** |
| ■ New Wholesaler<br>☐ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH _____ | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: Coloplast Corp.

Physical Address: 475 Riverside Parkway, Suite 400

City: Lithia Springs State: GA Zip: 30122

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 770-281-8440 Website: https://www.coloplast.us/

Name of Designated Representative (DR): Jason McGee

Licensing Company Email: N/A DR Email: usjcm@coloplast.com

| Entities the Wholesaler will Serve (✓ all applicable) | Products to be Handled or Wholesaled (✓ all applicable) | Type of Wholesaling (✓ all applicable) |
|---|---|---|
| ☐ Pharmacies | ☐ Dangerous Drugs | ☐ Manufacturer |
| ■ Practitioners | ☐ Controlled Substances | ■ Repacker |
| ■ Hospitals | ■ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ■ Wholesalers | ☐ Others: | ■ Warehouse |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ■ Others: DMEs | | ☐ Others: |

| Section 2: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✓ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | ✓ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | ✓ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✓ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| Reason/Charge | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| Name of Business/Industry/Entity | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

Date

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: N/A - Coloplast Corp. does not distribute drugs or controlled substances.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

**Section 4: Publicly Traded Corporation**

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: Delaware

Parent Company (if any): Coloplast A/S

Corporation/Organization Name: Coloplast Corp.

Mailing Address: 1601 West River Road North

City: Minneapolis State: MN Zip: 55411

Telephone: 1-800-788-0293 Email: uslegal@coloplast.com

Contact Person Name: General Counsel, Stephen Froehle

**Section 6: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

**Section 7: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | ✓ |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | ✓ | |
| 1. Copy of FDA registration Enclosed<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. Enclosed | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** Enclosed | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** Noted in cover letter | | ✓ | | |
| • **List of all partners and their percent ownership.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. Enclosed | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ Enclosed | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ Noted in cover letter | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** N/A | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** Enclosed | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** Enclosed | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ Enclosed | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). Enclosed | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Coloplast Corp.

Facility Name

Stephen G. Froehle

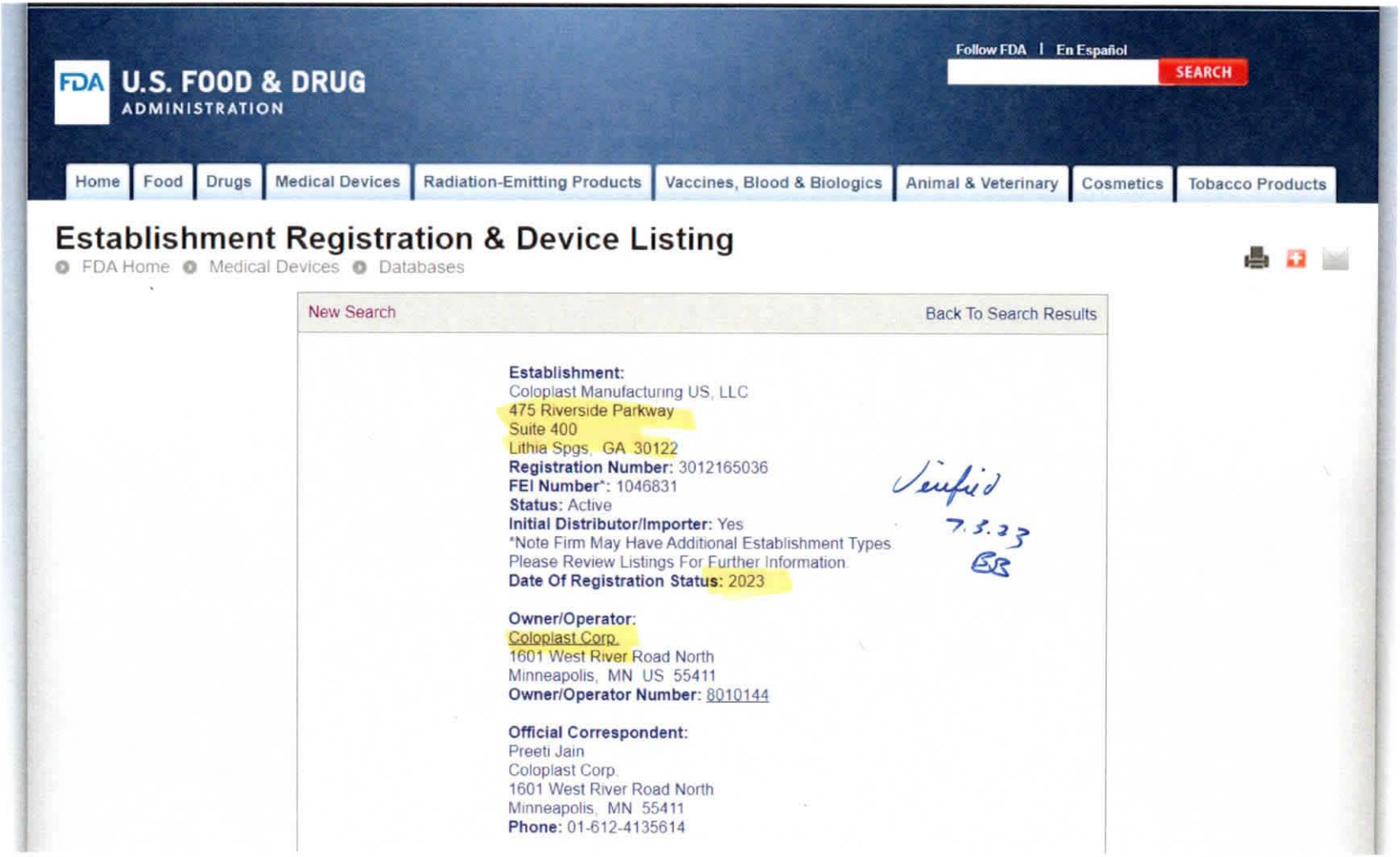
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

June 27, 2023

Date

| Board Use Only | Date Received: 7/3/23 | Amount: 1000 - CC |
|---|---|---|



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Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

# Establishment Registration & Device Listing

FDA Home ▸ Medical Devices ▸ Databases

New Search | Back To Search Results

**Establishment:**
Coloplast Manufacturing US, LLC
475 Riverside Parkway
Suite 400
Lithia Spgs, GA 30122
**Registration Number:** 3012165036
**FEI Number*:** 1046831
**Status:** Active
**Initial Distributor/Importer:** Yes
*Note Firm May Have Additional Establishment Types. Please Review Listings For Further Information.
**Date Of Registration Status:** 2023

Verified 7.3.23 BR

**Owner/Operator:**
Coloplast Corp.
1601 West River Road North
Minneapolis, MN US 55411
**Owner/Operator Number:** 8010144

**Official Correspondent:**
Preeti Jain
Coloplast Corp.
1601 West River Road North
Minneapolis, MN 55411
**Phone:** 01-612-4135614

# COLOPLAST CORP.
# CORPORATE GOVERNANCE SUMMARY

**Coloplast Corp.**

Directors:

Henrik Deneke
Manu Varma
Thomas NP Johns, Jr.

Officers:

Manu Varma, Chief Executive Officer
Thomas NP Johns, Jr., Vice President
Kimberly Ditter, Vice President
Shelley Mueller, Treasurer
Stephen G. Froehle, Secretary

# Delaware

The First State



I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "COLOPLAST CORP." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-THIRD DAY OF MAY, A.D. 2023.

Jeffrey W. Bullock, Secretary of State

4408961 8300

SR# 20232279556

Authentication: 203402238

Date: 05-23-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

JAMES WORTHINGTON
*Development Services Director*

RONALD M. ROBERTS, JR., AICP
*Planning & Zoning Manager*

# DOUGLAS COUNTY BOARD OF COMMISSIONERS

## OCCUPATIONAL TAX REGISTRATION

8700 Hospital Drive • Douglasville, GA 30134
Telephone (770) 920-7348 • Fax (770) 920-7482

## GENERAL BUSINESS LICENSE

**LICENSE EFFECTIVE 1/1/2022 TO 12/31/2022**

| | |
|---|---|
| REGISTRATION # | 101072 |
| OWNER: | JAMES A SCHUMER |
| BUSINESS: | COLOPLAST MANUFACTURING US, LLC |
| CONTACT: | JAMES A SCHUMER |
| | 475 RIVERSIDE PKWY |
| | LITHIA SPRINGS GA 30122 |
| BUSINESS TYPE: | LLC |
| EXEMPT STATUS: | NON EXEMPT |
| LOCATION TYPE: | Commercial |

**TOTAL CHARGED: $113.00**

Tax Class 3 — **$95.00**

488510 SERVICE/ SHIPPING AGENT FOR
493110 GENERAL WAREHOUSING & STORAGE

DEVELOPMENT SERVICES DIRECTOR

TC
AUTHORIZED INITIALS

**PENALTY IMPOSED BY LAW FOR FAILURE TO RENEW BEFORE 12/31/2022**
**PLACE ON DISPLAY**

ACORD®

# CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 09/14/2022

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

**PRODUCER**
Marsh USA Inc.
333 South 7th Street, Suite 1400
Minneapolis, MN 55402-2400
Attn: Minneapolis.CertRequest@marsh.com Fax 212-948-0114

**CONTACT NAME:**
**PHONE (A/C, No, Ext):** **FAX (A/C, No):**
**E-MAIL ADDRESS:**

| INSURER(S) AFFORDING COVERAGE | NAIC # |
|---|---|
| INSURER A : XL Insurance America, Inc. | 24554 |
| INSURER B : The Charter Oak Fire Insurance Company | 25615 |
| INSURER C : Phoenix Insurance Company | 25623 |
| INSURER D : QBE Insurance Corporation | 39217 |
| INSURER E : | |
| INSURER F : | |

**INSURED**
Coloplast Corp.
1601 West River Road
Minneapolis, MN 55411

**COVERAGES** **CERTIFICATE NUMBER:** CHI-009560485-08 **REVISION NUMBER:** 8

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

| INSR LTR | TYPE OF INSURANCE | ADDL INSD | SUBR WVD | POLICY NUMBER | POLICY EFF (MM/DD/YYYY) | POLICY EXP (MM/DD/YYYY) | LIMITS | | |
|---|---|---|---|---|---|---|---|---|---|
| A | X COMMERCIAL GENERAL LIABILITY | | | US00011271LI22A | 10/01/2022 | 10/01/2023 | EACH OCCURRENCE | $ | 5,000,000 |
| | X CLAIMS-MADE ☐ OCCUR | | | SIR: See Attached | | | DAMAGE TO RENTED PREMISES (Ea occurrence) | $ | 100,000 |
| | | | | | | | MED EXP (Any one person) | $ | 5,000 |
| | | | | | | | PERSONAL & ADV INJURY | $ | 5,000,000 |
| | GEN'L AGGREGATE LIMIT APPLIES PER: | | | | | | GENERAL AGGREGATE | $ | 5,000,000 |
| | X POLICY ☐ PRO-JECT ☐ LOC | | | | | | PRODUCTS - COMP/OP AGG | $ | 5,000,000 |
| | OTHER: | | | | | | | $ | |
| B | AUTOMOBILE LIABILITY | | | 8102G274522 | 10/01/2022 | 10/01/2023 | COMBINED SINGLE LIMIT (Ea accident) | $ | 2,000,000 |
| | X ANY AUTO | | | | | | BODILY INJURY (Per person) | $ | |
| | ☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS | | | | | | BODILY INJURY (Per accident) | $ | |
| | ☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY | | | | | | PROPERTY DAMAGE (Per accident) | $ | |
| | | | | | | | | $ | |
| | ☐ UMBRELLA LIAB ☐ OCCUR | | | | | | EACH OCCURRENCE | $ | |
| | ☐ EXCESS LIAB ☐ CLAIMS-MADE | | | | | | AGGREGATE | $ | |
| | ☐ DED ☐ RETENTION $ | | | | | | | $ | |
| C | WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N | | | UB0L9954032212E | 10/01/2022 | 10/01/2023 | X PER STATUTE ☐ OTH-ER | | |
| | ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBEREXCLUDED? Y | N / A | | | | | E.L. EACH ACCIDENT | $ | 1,000,000 |
| | (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below | | | | | | E.L. DISEASE - EA EMPLOYEE | $ | 1,000,000 |
| | | | | | | | E.L. DISEASE - POLICY LIMIT | $ | 1,000,000 |
| D | CYBER LIABILITY | | | QPL0769038 | 10/01/2022 | 10/01/2023 | EACH OCCURRENCE | | 1,000,000 |
| | (Claims Made) | | | SIR Value: $10,000,000 | | | AGGREGATE | | 1,000,000 |

**DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)**
Evidence of Insurance

**CERTIFICATE HOLDER**
Coloplast Corp.
1601 West River Road N.,
Minneapolis, MN 55411

**CANCELLATION**
SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

**AUTHORIZED REPRESENTATIVE**
Marsh USA Inc.

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The ACORD name and logo are registered marks of ACORD

AGENCY CUSTOMER ID: CN102734708
LOC #: Minneapolis

ACORD®

# ADDITIONAL REMARKS SCHEDULE



| AGENCY | NAMED INSURED |
|---|---|
| Marsh USA Inc. | Coloplast Corp.<br>1601 West River Road<br>Minneapolis, MN 55411 |
| POLICY NUMBER | |
| CARRIER / NAIC CODE | EFFECTIVE DATE: |

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

GENERAL LIABILITY SIR
$79,500 (500,000 DKK) per claim - non implant products and premises
$1,590,000 (10m DKK) per claim - all implants products (excluding penile implants)
$1,590,000 (10m DKK) per claimant - penile implants
Non-ranking deductible - each and every claim $5,963


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AGENCY CUSTOMER ID: CN102734708
LOC #: Minneapolis

# ADDITIONAL REMARKS SCHEDULE



| AGENCY | NAMED INSURED |
|---|---|
| Marsh USA Inc. | Coloplast Corp.<br>1601 West River Road<br>Minneapolis, MN 55411 |
| POLICY NUMBER | |
| CARRIER / NAIC CODE | EFFECTIVE DATE: |

## ADDITIONAL REMARKS

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$1,590,000 (10m DKK) per claimant - penile implants
Non-ranking deductible - each and every claim $5,963


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# NEVADA STATE BOARD OF PHARMACY

**985 Damonte Ranch Pkwy Suite 206**
**Reno, NV 89521**
**(775) 850-1440**
**Fax: (775) 850-1444**

## PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 20BSBJB5097

Application/License No. _____

Coloplast Manufacturing US, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 475 Riverside Parkway, Suite 400, Lithia Springs, GA 30122 (Address of Applicant/Principal), as PRINCIPAL, and Hartford Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of Connecticut (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1111 Northshore Dr., Knoxville, TN 37919 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on June 23, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

20BSBJB5097

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 23rd day of June, 2023.

APPLICANT/PRINCIPAL

Coloplast Manufacturing US, LLC

Authorized Representative

SURETY COMPANY

Hartford Fire Insurance Company

Surety Company's Representative

Bonnie Rice, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Lori Wright

Witness Andrea Allman

Countersigned by:

N/A
Nevada Resident Agent

# POWER OF ATTORNEY

**Direct Inquiries/Claims to:**
**THE HARTFORD**
**BOND, T-11**
**One Hartford Plaza**
**Hartford, Connecticut 06155**
**Bond.Claims@thehartford.com**
***call:* 888-266-3488 *or fax:* 860-757-5835**

**KNOW ALL PERSONS BY THESE PRESENTS THAT:**

**Agency Name:** MARSH USA LLC
**Agency Code:** 20-246454

- [X] **Hartford Fire Insurance Company,** a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company,** a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company,** a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company,** a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company,** a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois,** a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest,** a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast,** a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint
Bonnie Rice

its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by , and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:
Bond No. 20BSBJB5097
Naming Coloplast Manufacturing US, LLC as Principal,
and Nevada State Board of Pharmacy as Obligee,
in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

**In Witness Whereof,** and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

**STATE OF FLORIDA**
**COUNTY OF SEMINOLE** } **ss.** Lake Mary

On this 20th day of May, 2021, before me personally came Joelle LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Jessica Ciccone
My Commission HH 122280
Expires June 20, 2025

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of June 23, 2023.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

### Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Coloplast Corp. MDEG License # (if applicable): _____

Physical Address: 475 Riverside Parkway, Suite 400

City: Lithia Springs State: GA Zip: 30122

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 770-281-8440 Website: https://www.coloplast.us/

Licensing Company Email: N/A

### Section 2: Personal Information

First: Jason Middle: Craig Last: McGee

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] Crescent Pkwy, [redacted]

City: Atlanta State: GA Zip: 30339

Telephone: [redacted] Email: usjcm@coloplast.com

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | ✔ | |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✔ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| University of Georgia | | 08/04 - 05/07 | |
| Address | City | State | Zip |
| 102 Conner Hall | Athens | GA | 30602 |
| Diploma/Degree obtained, if any | | | |
| Master of Business Administration | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Univeristy of Central Florida | | 08/93 - 08/98 | |
| Address | City | State | Zip |
| 4000 Central Florida Blvd | Orlando | FL | 32816 |
| Diploma/Degree obtained, if any | | | |
| Bachelor of Science | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Lake Howell High School | | 08/89 - 05/93 | |
| Address | City | State | Zip |
| 4200 Dike Rd | Winter Park | FL | 32792 |
| Diploma/Degree obtained, if any | | | |
| Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 10/20 - Current | [redacted]Crescent Pkwy[redacted] | Atlanta | GA | 30339 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| 10/17 - 10/20 | [redacted]Rememberance Trace | Lawrenceville | GA | 30044 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| 10/03 - 10/17 | [redacted] Oak Drive | Snellville | GA | 30078 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |

**Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Coloplast Corp. | | | 03/19 - Current | |
| **Business Address** | | **City** | **State** | **Zip** |
| 475 Riverside Parkway, Suite 400 | | Lithia Springs | GA | 30122 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 770-281-8440 | Director, Regional Distribution | | 8,320 | |
| **Description of Duties** | | | | |
| Responsible for all warehouse and distribution operations. | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state? | | ✔ |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline. | | ✔ |

**Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| | | | | |
| Reason/Charge | | | | |
| | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| | | | | |
| Name of Business/Industry/Entity | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

6/27/23
Date

I, Jason McGee, **certify that as the MDEG Administrator for**

Coloplast Corp.,

**that I (initial that you have read and meet the following requirements):**

1. JCM Have a high school diploma or its equivalent;
2. JCM Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JCM Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JCM Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Jason McGee
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/27/23
Date

| Board Use Only | Date Received: 7-3-23 |
|---|---|

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

### Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Coloplast Corp.

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 475 Riverside Parkway, Suite 400

City: Lithia Springs State: GA Zip: 55411

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 770-281-8440 Website: https://www.coloplast.us/

Licensing Company Email: N/A

### Section 2: Personal Information

First: Jason Middle: Craig Last: McGee

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Crescent Pkwy [redacted]

City: Atlanta State: GA Zip: 30339

Telephone: [redacted] Email: usjcm@coloplast.com

Are you a citizen of the United States? ■ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | ✔ | |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✔ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| University of Georgia | | 08/04 - 05/07 | |
| **Address** | **City** | **State** | **Zip** |
| 102 Conner Hall | Athens | GA | 30602 |
| **Diploma/Degree obtained, if any** | | | |
| Master of Business Administration | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Univeristy of Central Florida | | 08/93 - 08/98 | |
| **Address** | **City** | **State** | **Zip** |
| 4000 Central Florida Blvd | Orlando | FL | 32816 |
| **Diploma/Degree obtained, if any** | | | |
| Bachelor of Science | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Lake Howell High School | | 08/89 - 05/93 | |
| **Address** | **City** | **State** | **Zip** |
| 4200 Dike Rd | Winter Park | FL | 32792 |
| **Diploma/Degree obtained, if any** | | | |
| Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 10/20 - Current | [redacted] Crescent Pkwy [redacted] | Atlanta | GA | 30339 |
| 10/17 - 10/20 | [redacted] Rememberance Trace | Lawrenceville | GA | 30044 |
| 10/03 - 10/17 | [redacted] Oak Drive | Snellville | GA | 30078 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| | | | | |
|---|---|---|---|---|
| Business Name: Coloplast Corp. | | | | From - To (MM/YY – MM/YY): 03/19 - Current |
| Business Address: 475 Riverside Parkway, Suite 400 | | City: Lithia Springs | State: GA | Zip: 30122 |
| Phone: 770-281-8440 | Title: Director, Regional Distribution | | | Number of Employed Hours: 8,320 |
| Description of Duties: Responsible for warehouse and distribution operations. | | | | |
| Business Name | | | | From - To (MM/YY – MM/YY) |
| Business Address | | City | State | Zip |
| Phone | Title | | | Number of Employed Hours |
| Description of Duties | | | | |
| Business Name | | | | From - To (MM/YY – MM/YY) |
| Business Address | | City | State | Zip |
| Phone | Title | | | Number of Employed Hours |
| Description of Duties | | | | |
| Business Name | | | | From - To (MM/YY – MM/YY) |
| Business Address | | City | State | Zip |
| Phone | Title | | | Number of Employed Hours |
| Description of Duties | | | | |
| Business Name | | | | From - To (MM/YY – MM/YY) |
| Business Address | | City | State | Zip |
| Phone | Title | | | Number of Employed Hours |
| Description of Duties | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| | | | | |
| Reason/Charge | | | | |
| | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| | | | | |
| Name of Business/Industry/Entity | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

6/27/23
Date

I, Jason McGee, **certify that as the designated representative for**

Coloplast Corp.,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. JCM I am at least 21 years of age;
3. JCM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JCM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JCM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JCM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JCM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jason McGee

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/27/23

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Jason McGee

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/27/23

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of GEORGIA, ss. County of FULTON

I, JASON McGEE, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

~~6/23~~ 6/27/23

**Date**

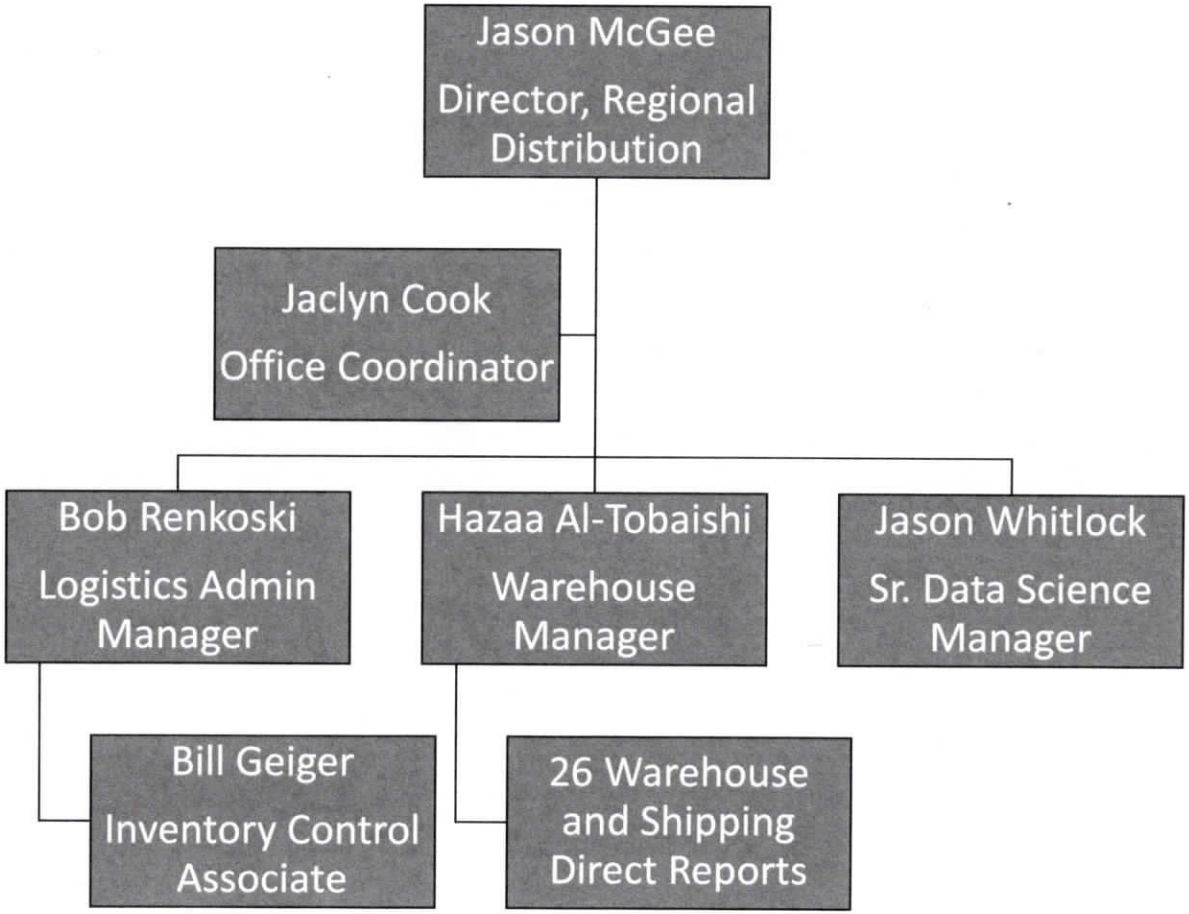
Subscribed and Sworn to before me this 21st day of June 2023

**Notary Public Signature**

NKENGE BROWN NOTARY PUBLIC FULTON COUNTY, GEORGIA MY COMMISSION EXPIRES MARCH 21, 2026

(Seal)

Employee List



Coloplast

The Personal Record History Record Application described in bullet 7 of GA Application Section 9 is not applicable to Coloplast Corp.

In a separate letter, copy attached, Coloplast is requesting, as discussed in a June 6, 2023 email from Mr. Cedars to me, a temporary license for the GA Applicant's facility.

Sincerely,

Aaron Rodriquez
Senior Legal Counsel, North America

CC: Executive Secretary Dave Wuest, Nevada BOP

Enclosures:
1) Wholesaler Application Package with Check Payment

Coloplast

June 29, 2023

Executive Secretary Dave Wuest
Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

Aaron Rodriquez
Senior Legal Counsel, North America
Mobile: 612-889-0672
Mail: usarodr@coloplast.com

Coloplast Corp
1601 West River Road North
Minneapolis, MN 55411
United States

Tel: 612.372.7400
Toll Free Number:
1.800.788.0293
www.coloplast.us

**RE: Coloplast Corp. Wholesaler Application – Lithia Springs, GA**

To Whom It May Concern:

By this letter, Coloplast Corp. is requesting a temporary wholesaler license for the Coloplast Corp. facility listed below. We are making this request at the same time as we are providing to the Nevada State Board of Pharmacy (BOP) our wholesaler application as discussed on a June 6, 2023 teleconference with me, Tara Farrington and from the BOP, Mr. Zunino, Mr. Wuest and Mr. Cedars. At the conclusion of that call, you sent me an email indicating that I should submit this request for Temporary Licensure on Coloplast letterhead and addressed to you. It is my understanding that, if approved, BOP staff will issue the "temp" license valid until the board meeting date which will be assigned to this application.

This request for temporary licensure is made for Coloplast Corp. (Coloplast) at this facility:

475 Riverside Parkway, Suite 400
Lithia Springs, GA 30122

Sincerely,

Aaron Rodriquez
Senior Legal Counsel, North America

# Nevada State Board of Pharmacy

985 Damonte Ranch Parkway, Suite 206 • Reno, NV 89521
(775) 850-1440 • FAX (775) 850-1444
Web Page: bop.nv.gov


March 22, 2023

Via Certified Mail and E-Mail (ukms@coloplast.com)

Coloplast Corp.
1601 West River Road
Minneapolis, MN 55411
Attn: Katy Herman, North American Compliance Manager

**CEASE-AND-DESIST and CITATION-AND-FINE ORDER: Case No. 23-072-O**
**Unlicensed Wholesaling Activity in Nevada**

Dear Ms. Herman:

The Nevada State Board of Pharmacy (Board) has determined that Coloplast Corp., a Minnesota-based wholesaler of medical devices and/or equipment, has been distributing its products into Nevada without a license as required by Nevada Revised Statutes (NRS) 639.233. Accordingly, pursuant to NRS 639.2895, you are hereby ordered to immediately **CEASE and DESIST** distributing into Nevada any such products that are restricted by federal law to sale by or on the order of a physician. Additionally, this notice shall serve as a **CITATION** pursuant to NRS 639.2895(2) for the unlicensed wholesaling of medical devices, equipment, and/or gases. Pursuant to NRS 639.2895(3), the Board has assessed an administrative fine against Coloplast Corp. in the amount of five thousand dollars ($5,000.00).

You must pay this administrative fine within 30 days of receipt of this citation, or otherwise contact Board staff to request an alternative payment plan. Payment must be by *cashier's check*, *certified check* or *money order* made payable to "State of Nevada, Office of the Treasurer," to be received at the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

You have the right to appeal this citation by submitting a written request for a hearing to the Board at the Board's Reno office no later than 30 days after receipt of this notice. *See* NRS 639.2895(2). Please be aware that the forgoing does not preclude the filing of administrative or criminal charges if deemed appropriate based upon evidence not currently available to the Board. If you have any questions, please do not hesitate to contact me at 775-850-1440 or zunino@pharmacy.nv.gov.

Sincerely,

/s/ Gregory L. Zunino
Gregory L. Zunino
Senior General Counsel

9171 9690 0935 0279 2906 80

# 4H

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

**Non-Refundable $1,000 Fee**

Rev (08/17/2022)

| Where is the facility located? | ☐ Nevada ■ Out-of-State |
|---|---|

| Type of Application (check applicable box) | | Wholesaler Business Type (check applicable box) |
|---|---|---|
| ■ New Wholesaler<br>☐ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH _____ | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

### Section 1: General Information

Facility Name: Coloplast Corp.

Physical Address: 1601 West River Road North

City: Minneapolis State: MN Zip: 55411

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 612-337-7800 Website: https://www.coloplast.us/

Name of Designated Representative (DR): Brent Binkowski

Licensing Company Email: N/A DR Email: usbbi@coloplast.com

| Entities the Wholesaler will Serve (✓ all applicable) | Products to be Handled or Wholesaled (✓ all applicable) | Type of Wholesaling (✓ all applicable) |
|---|---|---|
| ☐ Pharmacies | ☐ Dangerous Drugs | ■ Manufacturer |
| ■ Practitioners | ☐ Controlled Substances | ☐ Repacker |
| ■ Hospitals | ■ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ■ Wholesalers | ☐ Others: | ☐ Warehouse |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ■ Others: DMEs | | ☐ Others: |

| Section 2: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✓ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | ✓ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | ✓ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✓ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| Reason/Charge | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| Name of Business/Industry/Entity | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

Date

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: N/A - Coloplast Corp. does not distribute drugs or controlled substances.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

**Section 4: Publicly Traded Corporation**

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: Delaware

Parent Company (if any): Coloplast A/S

Corporation/Organization Name: Coloplast Corp.

Mailing Address: 1601 West River Road North

City: Minneapolis State: MN Zip: 55411

Telephone: 612-337-7800 Email: uslegal@coloplast.com

Contact Person Name: General Counsel, Stephen Froehle

**Section 6: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

**Section 7: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | ✓ |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | ✓ | |
| 1. Copy of FDA registration Enclosed<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. Enclosed | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** Enclosed | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** Noted in cover letter | | ✓ | | |
| • **List of all partners and their percent ownership.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. Enclosed | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ Enclosed | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ Noted in cover letter | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** N/A | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** Enclosed | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** Enclosed | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ Enclosed | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). Enclosed | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Coloplast Corp.

Facility Name

Stephen G. Froehle

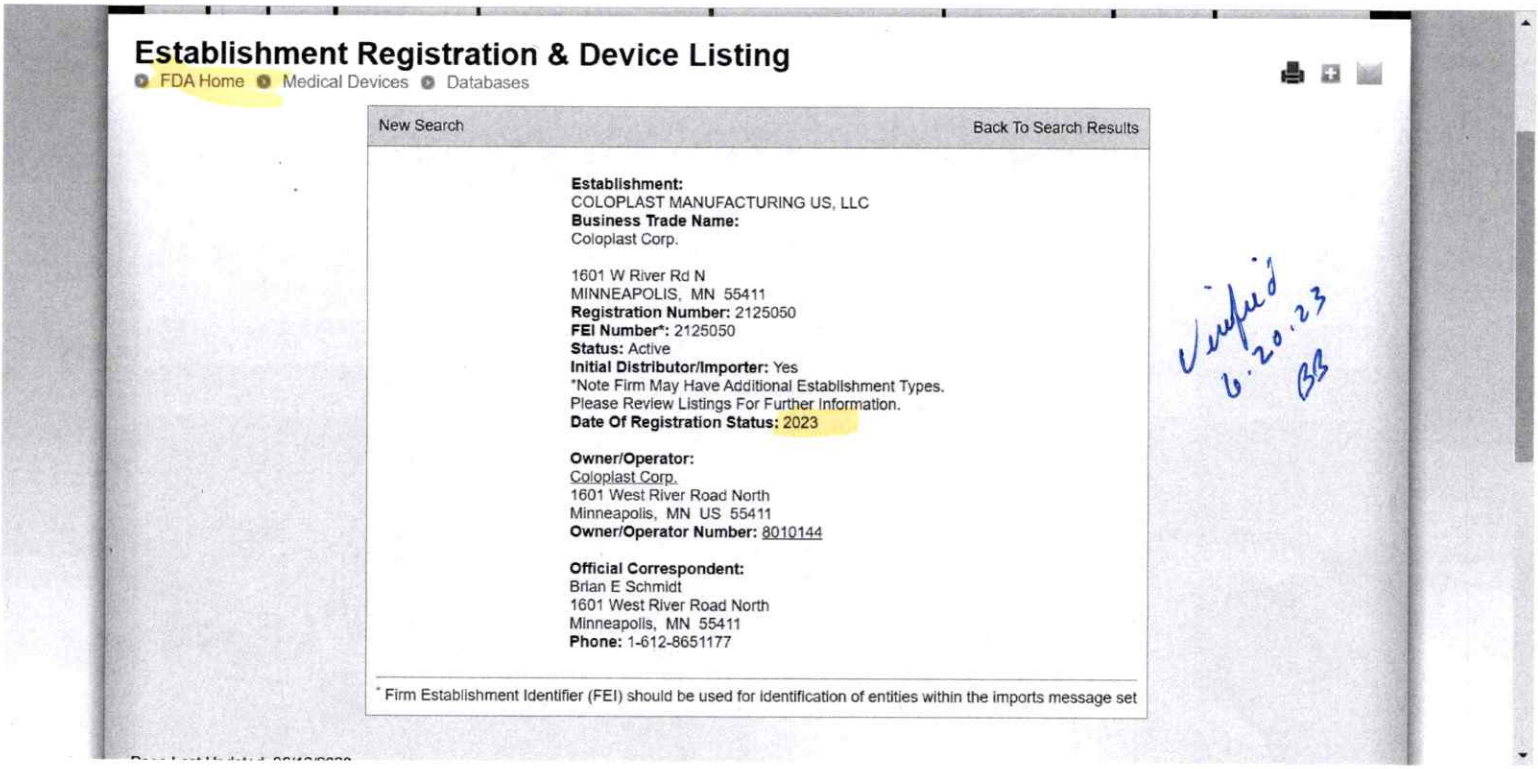
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

June 15, 2023

Date

| Board Use Only | Date Received: 6.20.23 | Amount: 1000.00 CK-97138 |
|---|---|---|



# Establishment Registration & Device Listing

FDA Home › Medical Devices › Databases

New Search | Back To Search Results

**Establishment:**
COLOPLAST MANUFACTURING US, LLC
**Business Trade Name:**
Coloplast Corp.

1601 W River Rd N
MINNEAPOLIS, MN 55411
**Registration Number:** 2125050
**FEI Number*:** 2125050
**Status:** Active
**Initial Distributor/Importer:** Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
**Date Of Registration Status:** 2023

**Owner/Operator:**
Coloplast Corp.
1601 West River Road North
Minneapolis, MN US 55411
**Owner/Operator Number:** 8010144

**Official Correspondent:**
Brian E Schmidt
1601 West River Road North
Minneapolis, MN 55411
**Phone:** 1-612-8651177

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Verified 6.20.23 BB

## Lauren Portinga

**From:** userfeesconfirmation@fda.hhs.gov
**Sent:** Wednesday, November 2, 2022 4:04 PM
**To:** Lauren Portinga; Lauren Portinga
**Subject:** FDA USER FEES Payment Confirmation #50379491

Your payment has been submitted to Pay.gov. Please refer to the details below.

| | |
|---|---|
| Account Holder Name: | **Coloplast Corp.** |
| Pay.gov Tracking ID: | **2729FJVF** |
| Agency Tracking ID: | **50379491** |
| Transaction Type: | **Sale** |
| Payment Amount: | **$ 6,493.00** |
| Transaction Date : | **NOVEMBER 02,2022 05:03:39 PM** |

Once the payment is applied in our system, you will receive a Payment Confirmation Number (PCN). Once you have both the PIN/PCN, you can log into the registration and listing system (www.access.fda.gov) to complete your registration.

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Help (./help/index.html)

DRLM Home (mainMenu.htm)

✔ Facility

✔ Products Listing

# Annual Registration Successful

Facility: COLOPLAST MANUFACTURING US, LLC, MINNEAPOLIS, Minnesota, UNITED STATES

You have successfully updated your registration and listing information for 2023.

Your registration will be valid through Dec 31, 2023.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2023.

***Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.***

You may contact the FDA with any questions at reglist@cdrh.fda.gov.

**The Owner/Operator Number for this Registration is: 8010144.**

## Facility Information

**Registration Number:**
**2125050**

**Initial Importer:**
**Y**

**Facility Name:**
**COLOPLAST MANUFACTURING US, LLC**

**Legal Name:**

**Address:**
**1601 W River Rd N,**
**MINNEAPOLIS, Minnesota, 55411, UNITED STATES**

**DUNS Number:**

**Foreign Trade Zone:**
**N**

**Facility URL:**
**www.coloplast.us**

**Other Business Trade Name(s):**
1. Coloplast Corp.

**Establishment located on a campus:**

## Owner/Operator Information

**Owner/Operator Number:**
8010144

**Contact Name:**
Brian E Schmidt

**Company:**
COLOPLAST CORP.

**Address:** 1601 West River Road North
Minneapolis, MINNESOTA, 55411, UNITED STATES

**Telephone:**
1 - 612 - 8651177

**Fax:**
-

**E-mail:** usbes@coloplast.com

**DUNS Number:**

## Official Correspondent Information

**Contact Name:**
Brian E Schmidt

**Company:**
COLOPLAST CORP.

**Address:** 1601 West River Road North
Minneapolis, MINNESOTA, 55411, UNITED STATES

**Telephone:**
1 - 612 - 8651177

**Fax:**
-

**E-mail:** usbes@coloplast.com

**DUNS Number:**

# COLOPLAST CORP.
# CORPORATE GOVERNANCE SUMMARY

**Coloplast Corp.**

Directors:

Henrik Deneke
Manu Varma
Thomas NP Johns, Jr.

Officers:

Manu Varma, Chief Executive Officer
Thomas NP Johns, Jr., Vice President
Kimberly Ditter, Vice President
Shelley Mueller, Treasurer
Stephen G. Froehle, Secretary

# Delaware

The First State



*I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "COLOPLAST CORP." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-THIRD DAY OF MAY, A.D. 2023.*

Jeffrey W. Bullock, Secretary of State

4408961 8300

SR# 20232279556

Authentication: 203402238

Date: 05-23-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

MINNESOTA
BOARD OF PHARMACY

Minnesota Health Licensing Boards

# Minnesota Board of Pharmacy

License/Registration Verification as of June 9, 2023

| | |
|---|---|
| Name | Coloplast Manufacturing US, LLC |
| Address | 1940 Commerce Drive<br>P.O. Box 8300<br>North Mankato, MN 56002-8300 |

## License/Registration Information

| | |
|---|---|
| Type | Manufacturer License |
| Category | |
| Number | 460281 |
| Status | Active |
| Original Issue Date | 06/16/1993 |
| Date | 06/08/2023 |
| Expiration Date | 05/31/2024 |
| Disciplinary Action | No |

**This data is authorized to be used as primary source verification of a Minnesota License.**

*Disclaimer: While we believe this information to be reliable, human or mechanical error remains a possibility, as does delay in the posting or updating of information. Therefore there is no guarantee as to the accuracy, completeness, timeliness, or currency of the data listed in the individual section. The Board is not responsible for the use, or result obtained from the use, of this information.*

## Business Record Details »

Minnesota Business Name
**Coloplast Corp.**

**Business Type**
Business Corporation (Foreign)

**File Number**
2529900-4

**Filing Date**
10/02/2007

**Renewal Due Date**
12/31/2023

**Registered Agent(s)**
CORPORATION SERVICE COMPANY

**MN Statute**
303

**Home Jurisdiction**
Delaware

**Status**
Active / In Good Standing

**Registered Office Address**
2345 Rice Street
Suite 230
Roseville, MN 55113-5603
USA

**Chief Executive Officer**
Manu Varma
1601 West River Road N
Minneapolis, MN 55411
United States

ACORD®

# CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
09/14/2022

**THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.**

**IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).**

| | |
|---|---|
| **PRODUCER**<br>Marsh USA Inc.<br>333 South 7th Street, Suite 1400<br>Minneapolis, MN 55402-2400<br>Attn: Minneapolis.CertRequest@marsh.com Fax 212-948-0114 | **CONTACT NAME:**<br>**PHONE (A/C, No, Ext):** **FAX (A/C, No):**<br>**E-MAIL ADDRESS:** |
| **INSURED**<br>Coloplast Corp.<br>1601 West River Road<br>Minneapolis, MN 55411 | **INSURER(S) AFFORDING COVERAGE** — **NAIC #**<br>**INSURER A :** XL Insurance America, Inc. — 24554<br>**INSURER B :** The Charter Oak Fire Insurance Company — 25615<br>**INSURER C :** Phoenix Insurance Company — 25623<br>**INSURER D :** QBE Insurance Corporation — 39217<br>**INSURER E :**<br>**INSURER F :** |

**COVERAGES** **CERTIFICATE NUMBER:** CHI-009560485-08 **REVISION NUMBER:** 8

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

| INSR LTR | TYPE OF INSURANCE | ADDL INSD | SUBR WVD | POLICY NUMBER | POLICY EFF (MM/DD/YYYY) | POLICY EXP (MM/DD/YYYY) | LIMITS | |
|---|---|---|---|---|---|---|---|---|
| A | X **COMMERCIAL GENERAL LIABILITY**<br>X CLAIMS-MADE ☐ OCCUR<br>GEN'L AGGREGATE LIMIT APPLIES PER:<br>X POLICY ☐ PRO-JECT ☐ LOC<br>OTHER: | | | US00011271LI22A<br>SIR: See Attached | 10/01/2022 | 10/01/2023 | EACH OCCURRENCE<br>DAMAGE TO RENTED PREMISES (Ea occurrence)<br>MED EXP (Any one person)<br>PERSONAL & ADV INJURY<br>GENERAL AGGREGATE<br>PRODUCTS - COMP/OP AGG | $ 5,000,000<br>$ 100,000<br>$ 5,000<br>$ 5,000,000<br>$ 5,000,000<br>$ 5,000,000 |
| B | **AUTOMOBILE LIABILITY**<br>X ANY AUTO<br>OWNED AUTOS ONLY ☐ SCHEDULED AUTOS<br>HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY | | | 8102G274522 | 10/01/2022 | 10/01/2023 | COMBINED SINGLE LIMIT (Ea accident)<br>BODILY INJURY (Per person)<br>BODILY INJURY (Per accident)<br>PROPERTY DAMAGE (Per accident) | $ 2,000,000<br>$<br>$<br>$ |
| | ☐ **UMBRELLA LIAB** ☐ OCCUR<br>☐ **EXCESS LIAB** ☐ CLAIMS-MADE<br>☐ DED ☐ RETENTION $ | | | | | | EACH OCCURRENCE<br>AGGREGATE | $<br>$ |
| C | **WORKERS COMPENSATION AND EMPLOYERS' LIABILITY**<br>ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? **(Mandatory in NH)** Y / N: Y<br>If yes, describe under DESCRIPTION OF OPERATIONS below | N / A | | UB0L9954032212E | 10/01/2022 | 10/01/2023 | X PER STATUTE ☐ OTH-ER<br>E.L. EACH ACCIDENT<br>E.L. DISEASE - EA EMPLOYEE<br>E.L. DISEASE - POLICY LIMIT | $ 1,000,000<br>$ 1,000,000<br>$ 1,000,000 |
| D | CYBER LIABILITY<br>(Claims Made) | | | QPL0769038<br>SIR Value: $10,000,000 | 10/01/2022 | 10/01/2023 | EACH OCCURRENCE<br>AGGREGATE | 1,000,000<br>1,000,000 |

**DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)**
Evidence of Insurance

**CERTIFICATE HOLDER**

Coloplast Corp.
1601 West River Road N.,
Minneapolis, MN 55411

**CANCELLATION**

**SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.**

**AUTHORIZED REPRESENTATIVE**

Marsh USA Inc.

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**The ACORD name and logo are registered marks of ACORD**

AGENCY CUSTOMER ID: CN102734708
LOC #: Minneapolis

# ADDITIONAL REMARKS SCHEDULE



| AGENCY | NAMED INSURED |
|---|---|
| Marsh USA Inc. | Coloplast Corp.<br>1601 West River Road<br>Minneapolis, MN 55411 |
| POLICY NUMBER | |
| CARRIER / NAIC CODE | EFFECTIVE DATE: |

## ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

GENERAL LIABILITY SIR
$79,500 (500,000 DKK) per claim - non implant products and premises
$1,590,000 (10m DKK) per claim - all implants products (excluding penile implants)
$1,590,000 (10m DKK) per claimant - penile implants
Non-ranking deductible - each and every claim $5,963


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# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

## PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 20BSBJB3301

Application/License No. n/a

Coloplast Corp., doing or intending to do business as a
(Applicant/Principal)
pharmaceutical wholesaler, whose address for purposes of service is
1601 West River Road, Minneapolis, MN 55411, as
(Address of Applicant/Principal)
PRINCIPAL, and Hartford Fire Insurance Company, a
(Surety Company)
corporation organized under the laws of the state of Connecticut
(State of Incorporation)
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
1111 Northshore Dr., Knoxville, TN 37919 as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on June 16, 2023.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

20BSBJB3301

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 8th day of June, 2023.

APPLICANT/PRINCIPAL

Coloplast Corp.

Authorized Representative

SURETY COMPANY

Hartford Fire Insurance Company

Surety Company's Representative

Bonnie Rice, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

# POWER OF ATTORNEY

**Direct Inquiries/Claims to:**
THE HARTFORD
BOND, T-11
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
*call:* 888-266-3488 *or fax:* 860-757-5835

**KNOW ALL PERSONS BY THESE PRESENTS THAT:**

**Agency Name:** MARSH USA INC
**Agency Code:** 20-246454

- [X] **Hartford Fire Insurance Company,** a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company,** a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company,** a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company,** a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company,** a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois,** a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest,** a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast,** a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint
Bonnie Rice

its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by , and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:
Bond No. 20BSBJB3301
Naming Coloplast Corp. as Principal,
and Nevada State Board of Pharmacy as Obligee,
in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

**In Witness Whereof,** and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

**STATE OF FLORIDA**
**COUNTY OF SEMINOLE** } **ss.** Lake Mary

On this 20th day of May, 2021, before me personally came Joelle LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Jessica Ciccone
My Commission HH 122280
Expires June 20, 2025

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of June 8, 2023.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

**NEVADA STATE BOARD OF PHARMACY**

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

# Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of MDEG Coloplast Corp. MDEG License # (if applicable) _____

Physical Address 1601 West River Road North

City Minneapolis State MN Zip 55411

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 612-337-7800 Website https://www.coloplast.us/

Licensing Company Email N/A

**Section 2: Personal Information**

First Brent Middle Anthony Last Binkowski

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] St. Paul Avenue

City Minneapolis State MN Zip 55416

Telephone [redacted] Email usbbi@coloplast.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| University of Minnesota | | 09/02 - 09/05 | |
| **Address** | **City** | **State** | **Zip** |
| 319 15th Avenue | Minneapolis | MN | 55455 |
| Diploma/Degree obtained, if any | | | |
| Masters of Business Administration | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| University of Wisconsin - Stout | | 09/87 - 06/93 | |
| **Address** | **City** | **State** | **Zip** |
| 712 Broadway Street | Menomonie | WI | 54751 |
| Diploma/Degree obtained, if any | | | |
| Bachelor of Science - Engineering | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Elmwood High School | | 5/83 - 5/87 | |
| **Address** | **City** | **State** | **Zip** |
| 213 S Scott Street | Elmwood | WI | 54740 |
| Diploma/Degree obtained, if any | | | |
| High School Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 06/15 - 06/23 | [redacted] St. Paul Avenue | Minneapolis | MN | 55416 |
| 02/13 - 06/15 | [redacted] Sitio Del Mar | Carlsbad | CA | 92009 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Coloplast Corp. | | | 06/20 - 06/23 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 1601 West River Road North | | Minneapolis | MN | 55411 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 612-337-7800 | VP of Operations | | 6240 | |
| **Description of Duties** | | | | |
| VP of Operations - responsible for all manufacturing and supply chain operations. | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

Continue on next page if additional space is needed.

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state? | | ✓ |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline. | | ✓ |

**Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # _____. **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted) Date

I, Brent Binkowski, **certify that as the MDEG Administrator for**

Coloplast Corp.,

**that I (initial that you have read and meet the following requirements):**

1. BAB Have a high school diploma or its equivalent;
2. BAB Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. BAB Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. BAB Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Brent Binkowski
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

June 15, 2023
Date

| Board Use Only | Date Received: |
|---|---|

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

**Section 1: Pharmacy/Wholesaler Information**

Name of Pharmacy/Wholesaler Coloplast Corp.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 1601 West River Road North

City Minneapolis State MN Zip 55411

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 612-337-7800 Website https://www.coloplast.us/

Licensing Company Email N/A

**Section 2: Personal Information**

First Brent Middle Anthony Last Binkowski

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]St. Paul Avenue

City Minneapolis State MN Zip 55416

Telephone [redacted] Email usbbi@coloplast.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| University of Minnesota | | 09/02 - 09/05 | |
| Address | City | State | Zip |
| 319 15th Avenue | Minneapolis | MN | 55455 |
| Diploma/Degree obtained, if any | | | |
| Masters of Business Administration | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| University of Wisconsin - Stout | | 09/87 - 06/93 | |
| Address | City | State | Zip |
| 712 Broadway Street | Menomonie | WI | 54751 |
| Diploma/Degree obtained, if any | | | |
| Bachelor of Science - Engineering | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Elmwood High School | | 5/83 - 5/87 | |
| Address | City | State | Zip |
| 213 S Scott Street | Elmwood | WI | 54740 |
| Diploma/Degree obtained, if any | | | |
| High School Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 06/15 - 06/23 | [redacted] St. Paul Avenue | Minneapolis | MN | 55416 |
| 02/13 - 06/15 | [redacted] Sitio Del Mar | Carlsbad | CA | 92009 |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
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**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Coloplast Corp. | | | 06/20 - 06/23 |
| **Business Address** | **City** | **State** | **Zip** |
| 1601 West River Road North | Minneapolis | MN | 55411 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| 612-337-7800 | VP of Operations | 6240 | |
| **Description of Duties** | | | |
| VP of Operations - responsible for all manufacturing and supply chain operations. | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY - MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✓ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✓ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✓ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # _____. **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| | | | | |
| Reason/Charge | | | | |
| | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| | | | | |
| Name of Business/Industry/Entity | | | | |
| | | | | |

**Provide explanation below:**

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Brent Binkowski, **certify that as the designated representative for**

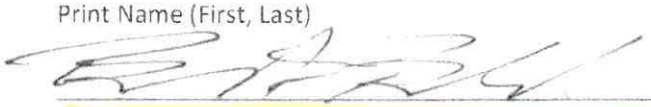
Coloplast Corp.,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. BAB I am at least 21 years of age;
3. BAB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. BAB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. BAB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. BAB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. BAB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Brent Binkowski

Print Name (First, Last)



Original Signature (electronic, copies or stamps not accepted)

June 15, 2023

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Brent Binkowski

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

June 15, 2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

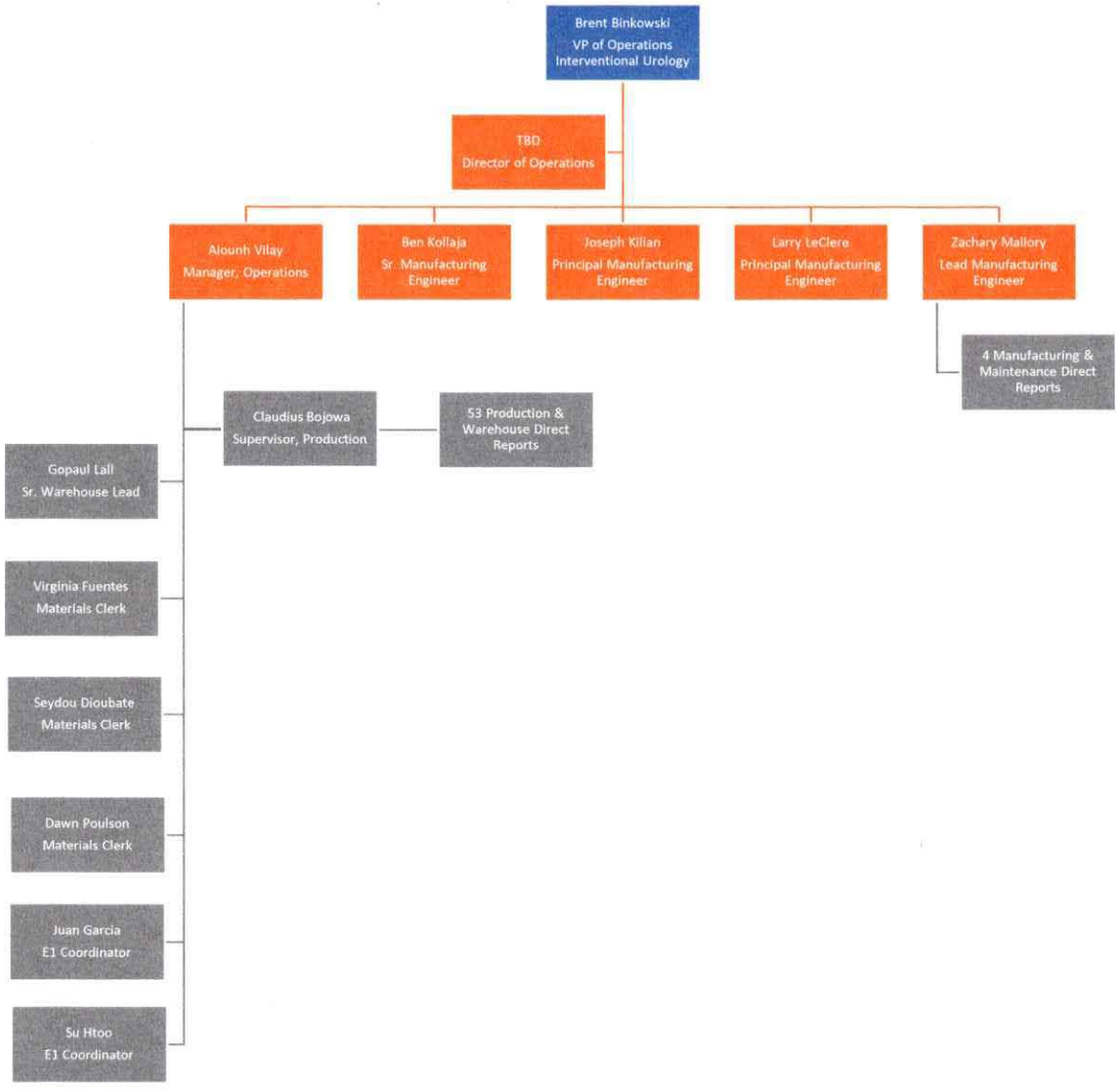
**Date**

Subscribed and Sworn to before me this _____ day of _____.

**Notary Public Signature**

**(Seal)**

## Employee List



# 41

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

**Non-Refundable $1,000 Fee**

Rev (08/17/2022)

| Where is the facility located? | ☐ Nevada ■ Out-of-State |
|---|---|

| Type of Application (check applicable box) | | Wholesaler Business Type (check applicable box) |
|---|---|---|
| ■ New Wholesaler<br>☐ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH _____ | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: Coloplast Corp.

Physical Address: 1940 Commerce Drive

City: North Mankato State: MN Zip: 56003

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 507-870-4056 Website: https://www.coloplast.us/

Name of Designated Representative (DR): Matthew Nuytten

Licensing Company Email: N/A DR Email: usmen@coloplast.com

| Entities the Wholesaler will Serve (✓ all applicable) | Products to be Handled or Wholesaled (✓ all applicable) | Type of Wholesaling (✓ all applicable) |
|---|---|---|
| ☐ Pharmacies | ☐ Dangerous Drugs | ■ Manufacturer |
| ■ Practitioners | ☐ Controlled Substances | ■ Repacker |
| ■ Hospitals | ■ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ■ Wholesalers | ☐ Others: | ■ Warehouse |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ■ Others: DMEs | | ☐ Others: |

| Section 2: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✓ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | ✓ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | ✓ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✓ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

Date

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: N/A - Coloplast Corp. does not distribute drugs or controlled substances.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

**Section 4: Publicly Traded Corporation**

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: Delaware

Parent Company (if any): Coloplast A/S

Corporation/Organization Name: Coloplast Corp.

Mailing Address: 1601 West River Road North

City: Minneapolis State: MN Zip: 55411

Telephone: 1-800-788-0293 Email: uslegal@coloplast.com

Contact Person Name: General Counsel, Stephen Froehle

**Section 6: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

**Section 7: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | ✓ |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | ✓ | |
| 1. Copy of FDA registration Enclosed<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. Enclosed | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** Enclosed | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** Noted in cover letter | | ✓ | | |
| • **List of all partners and their percent ownership.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. Enclosed | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ Enclosed | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ Noted in cover letter | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** N/A | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** Enclosed | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** Enclosed | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ Enclosed | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). Enclosed | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Coloplast Corp.

Facility Name

Stephen G. Froehle

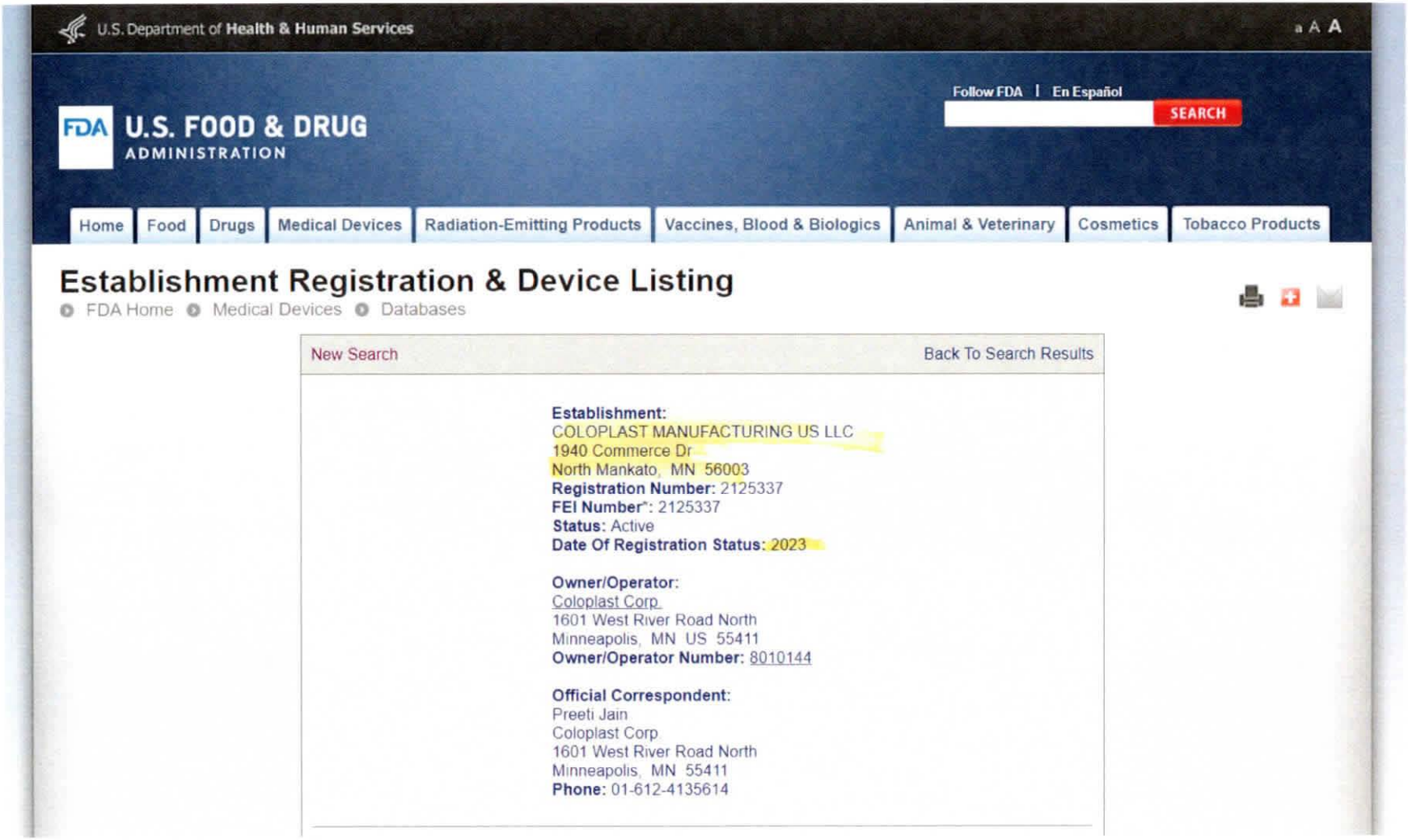
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

June 27, 2023

Date

| Board Use Only | Date Received: 7/3/23 | Amount: 1000-CC |
|---|---|---|



U.S. Department of Health & Human Services

a A A

FDA U.S. FOOD & DRUG ADMINISTRATION

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# Establishment Registration & Device Listing

FDA Home › Medical Devices › Databases

New Search | Back To Search Results

**Establishment:**
COLOPLAST MANUFACTURING US LLC
1940 Commerce Dr
North Mankato, MN 56003
**Registration Number:** 2125337
**FEI Number*:** 2125337
**Status:** Active
**Date Of Registration Status:** 2023

**Owner/Operator:**
Coloplast Corp
1601 West River Road North
Minneapolis, MN US 55411
**Owner/Operator Number:** 8010144

**Official Correspondent:**
Preeti Jain
Coloplast Corp
1601 West River Road North
Minneapolis, MN 55411
**Phone:** 01-612-4135614

# COLOPLAST CORP.
# CORPORATE GOVERNANCE SUMMARY

**Coloplast Corp.**

Directors:

Henrik Deneke
Manu Varma
Thomas NP Johns, Jr.

Officers:

Manu Varma, Chief Executive Officer
Thomas NP Johns, Jr., Vice President
Kimberly Ditter, Vice President
Shelley Mueller, Treasurer
Stephen G. Froehle, Secretary

# Delaware

The First State



I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "COLOPLAST CORP." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-THIRD DAY OF MAY, A.D. 2023.

Jeffrey W. Bullock, Secretary of State

4408961 8300

SR# 20232279556

Authentication: 203402238

Date: 05-23-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

MINNESOTA
BOARD OF PHARMACY

Minnesota Health Licensing Boards

# Minnesota Board of Pharmacy

License/Registration Verification as of June 9, 2023

| | |
|---|---|
| Name | Coloplast Manufacturing US, LLC |
| Address | 1940 Commerce Drive<br>P.O. Box 8300<br>North Mankato, MN 56002-8300 |

## License/Registration Information

| | |
|---|---|
| Type | Manufacturer License |
| Category | |
| Number | 460281 |
| Status | Active |
| Original Issue Date | 06/16/1993 |
| Date | 06/08/2023 |
| Expiration Date | 05/31/2024 |
| Disciplinary Action | No |

**This data is authorized to be used as primary source verification of a Minnesota License.**

*Disclaimer: While we believe this information to be reliable, human or mechanical error remains a possibility, as does delay in the posting or updating of information. Therefore there is no guarantee as to the accuracy, completeness, timeliness, or currency of the data listed in the individual section. The Board is not responsible for the use, or result obtained from the use, of this information.*

ACORD®

# CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
09/14/2022

**THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.**

**IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).**

**PRODUCER**
Marsh USA Inc.
333 South 7th Street, Suite 1400
Minneapolis, MN 55402-2400
Attn: Minneapolis.CertRequest@marsh.com Fax 212-948-0114

**CONTACT NAME:**
**PHONE (A/C, No, Ext):** **FAX (A/C, No):**
**E-MAIL ADDRESS:**

| INSURER(S) AFFORDING COVERAGE | NAIC # |
|---|---|
| **INSURER A** : XL Insurance America, Inc. | 24554 |
| **INSURER B** : The Charter Oak Fire Insurance Company | 25615 |
| **INSURER C** : Phoenix Insurance Company | 25623 |
| **INSURER D** : QBE Insurance Corporation | 39217 |
| **INSURER E** : | |
| **INSURER F** : | |

**INSURED**
Coloplast Corp.
1601 West River Road
Minneapolis, MN 55411

**COVERAGES** **CERTIFICATE NUMBER:** CHI-009560485-08 **REVISION NUMBER:** 8

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

| INSR LTR | TYPE OF INSURANCE | ADDL INSD | SUBR WVD | POLICY NUMBER | POLICY EFF (MM/DD/YYYY) | POLICY EXP (MM/DD/YYYY) | LIMITS | | |
|---|---|---|---|---|---|---|---|---|---|
| A | X **COMMERCIAL GENERAL LIABILITY**<br>X CLAIMS-MADE ☐ OCCUR<br>GEN'L AGGREGATE LIMIT APPLIES PER:<br>X POLICY ☐ PRO-JECT ☐ LOC<br>☐ OTHER: | | | US00011271LI22A<br>SIR: See Attached | 10/01/2022 | 10/01/2023 | EACH OCCURRENCE<br>DAMAGE TO RENTED PREMISES (Ea occurrence)<br>MED EXP (Any one person)<br>PERSONAL & ADV INJURY<br>GENERAL AGGREGATE<br>PRODUCTS - COMP/OP AGG<br>☐ | $<br>$<br>$<br>$<br>$<br>$<br>$ | 5,000,000<br>100,000<br>5,000<br>5,000,000<br>5,000,000<br>5,000,000 |
| B | **AUTOMOBILE LIABILITY**<br>X ANY AUTO<br>☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS<br>☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY | | | 8102G274522 | 10/01/2022 | 10/01/2023 | COMBINED SINGLE LIMIT (Ea accident)<br>BODILY INJURY (Per person)<br>BODILY INJURY (Per accident)<br>PROPERTY DAMAGE (Per accident)<br>☐ | $<br>$<br>$<br>$<br>$ | 2,000,000 |
| | ☐ **UMBRELLA LIAB** ☐ OCCUR<br>☐ **EXCESS LIAB** ☐ CLAIMS-MADE<br>☐ DED ☐ RETENTION $ | | | | | | EACH OCCURRENCE<br>AGGREGATE<br>☐ | $<br>$<br>$ | |
| C | **WORKERS COMPENSATION AND EMPLOYERS' LIABILITY** Y / N<br>ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBEREXCLUDED? Y<br>**(Mandatory in NH)**<br>If yes, describe under DESCRIPTION OF OPERATIONS below | N / A | | UB0L9954032212E | 10/01/2022 | 10/01/2023 | X PER STATUTE ☐ OTH-ER<br>E.L. EACH ACCIDENT<br>E.L. DISEASE - EA EMPLOYEE<br>E.L. DISEASE - POLICY LIMIT | $<br>$<br>$ | 1,000,000<br>1,000,000<br>1,000,000 |
| D | CYBER LIABILITY<br>(Claims Made) | | | QPL0769038<br>SIR Value: $10,000,000 | 10/01/2022 | 10/01/2023 | EACH OCCURRENCE<br>AGGREGATE | | 1,000,000<br>1,000,000 |

**DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)**
Evidence of Insurance

**CERTIFICATE HOLDER**
Coloplast Corp.
1601 West River Road N.,
Minneapolis, MN 55411

**CANCELLATION**
**SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.**

**AUTHORIZED REPRESENTATIVE**
Marsh USA Inc.

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AGENCY CUSTOMER ID: CN102734708
LOC #: Minneapolis

# ADDITIONAL REMARKS SCHEDULE



| AGENCY | NAMED INSURED |
|---|---|
| Marsh USA Inc. | Coloplast Corp.<br>1601 West River Road<br>Minneapolis, MN 55411 |
| POLICY NUMBER | |
| CARRIER / NAIC CODE | EFFECTIVE DATE: |

## ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

GENERAL LIABILITY SIR
$79,500 (500,000 DKK) per claim - non implant products and premises
$1,590,000 (10m DKK) per claim - all implants products (excluding penile implants)
$1,590,000 (10m DKK) per claimant - penile implants
Non-ranking deductible - each and every claim $5,963


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# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

## PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 20BSBGH2397

Application/License No. _____

Coloplast Manufacturing US, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1940 Commerce Drive North Mankato, MN 56003 (Address of Applicant/Principal), as PRINCIPAL, and Hartford Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of Connecticut (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1111 Northshore Dr., Knoxville, TN 37919 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on June 23, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

20BSBJB5097

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 23rd day of June, 2023.

APPLICANT/PRINCIPAL

Coloplast Manufacturing US, LLC

Authorized Representative

SURETY COMPANY

Hartford Fire Insurance Company

Surety Company's Representative

Bonnie Rice, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Lori Wright

Witness Andrea Allman

Countersigned by:

N/A
Nevada Resident Agent

# POWER OF ATTORNEY

*Direct Inquiries/Claims to:*
**THE HARTFORD**
**BOND, T-11**
**One Hartford Plaza**
**Hartford, Connecticut 06155**
**Bond.Claims@thehartford.com**
*call:* **888-266-3488** *or fax:* **860-757-5835**

**KNOW ALL PERSONS BY THESE PRESENTS THAT:**

**Agency Name:** MARSH USA LLC
**Agency Code:** 20-246454

- [X] **Hartford Fire Insurance Company,** a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company,** a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company,** a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company,** a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company,** a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois,** a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest,** a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast,** a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint
Bonnie Rice

its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by , and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:
Bond No. 20BSBJB5095
Naming Coloplast Manufacturing US, LLC as Principal,
and Nevada State Board of Pharmacy as Obligee,
in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

**In Witness Whereof,** and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

**STATE OF FLORIDA**
**COUNTY OF SEMINOLE** } ss. Lake Mary

On this 20th day of May, 2021, before me personally came Joelle LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Jessica Ciccone
My Commission HH 122280
Expires June 20, 2025

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of June 23, 2023.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

**NAC 639.694**

1. **Each medical products provider or medical products wholesaler shall employ an administrator at all times. The administrator must:**
   a. Be a natural person;
   b. Have a high school diploma or its equivalent;
   c. Have:
      i. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
      ii. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
   d. Be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
   e. Be approved by the Board.
2. The administrator shall ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.
3. A medical products provider or medical products wholesaler shall notify the staff of the Board of the cessation of employment of an administrator within 3 business days after the cessation of the employment. A medical products provider or medical products wholesaler shall notify the staff of the Board of the employment of a new administrator within 3 business days after the beginning of the employment.
4. A medical products provider or medical products wholesaler may not operate for more than 10 business days without an administrator. The Board may summarily suspend the operation of a business or facility that operates without an administrator.

**NAC 639.6946**

1. Except as otherwise provided in NAC 639.6945, a medical products provider shall:
   a. Provide services for all medical products sold, leased or otherwise provided by the medical products provider, including, without limitation, set up, repair and maintenance.
   b. Employ an administrator and other employees sufficient to provide the services described in paragraph (a).

**NAC 639.6957**

1. A medical products wholesaler shall:
   a. Employ a facility administrator and other employees sufficient to operate, set up, repair, maintain and service all medical products sold, leased or otherwise provided by the medical products wholesaler.

**Please mail this completed application and all other required documents with your MDEG and/or Wholesaler Application to the address indicated above.**

If you have any questions, please contact the Nevada State Board of Pharmacy at 775-850-1440 or by email at pharmacy@pharmacy.nv.gov.

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of MDEG Coloplast Corp. MDEG License # (if applicable) _____

Physical Address 1940 Commerce Drive

City North Mankato State MN Zip 56003

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 507-870-4056 Website https://www.coloplast.us/

Licensing Company Email N/A

**Section 2: Personal Information**

First Matthew Middle Eric Last Nuytten

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] 222nd St

City Lake Crystal State MN Zip 56055

Telephone [redacted] Email usmen@coloplast.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✓ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Central Lakes College | | 09/94 - 05/97 | |
| Address | City | State | Zip |
| 501 W College Drive | Staples | MN | 56479 |
| Diploma/Degree obtained, if any | | | |
| Degree in Robotics and Automated Systems | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| St. Mary's School | | 9/81 - 05/94 | |
| Address | City | State | Zip |
| 104 Saint Mary's Street NW | Sleepy Eye | MN | 56085 |
| Diploma/Degree obtained, if any | | | |
| High School Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 06/20-Current | [redacted]222nd St. | Lake Crystal | MN | 56055 |
| 06/03-06/20 | [redacted]Charlotte Dr. | Lake Crystal | MN | 56055 |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| | | | | |
|---|---|---|---|---|
| Business Name: Coloplast Corp. | | | From - To (MM/YY – MM/YY): 04/03-Current | |
| Business Address: 1940 Commerce Drive | | City: North Mankato | State: MN | Zip: 56003 |
| Phone: 507-870-4056 | Title: Director, Manufacturing Mankato | | Number of Employed Hours: 41,920 | |
| Description of Duties: Responsible for all manufacturing and supply chain operations, quality and R&D. | | | | |
| Business Name | | | From - To (MM/YY – MM/YY) | |
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |
| Business Name | | | From - To (MM/YY – MM/YY) | |
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |
| Business Name | | | From - To (MM/YY – MM/YY) | |
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |
| Business Name | | | From - To (MM/YY – MM/YY) | |
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state? | | ✓ |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline. | | ✓ |

**Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| | | | | |
| Reason/Charge | | | | |
| | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| | | | | |
| Name of Business/Industry/Entity | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted) Date

I, Matthew Nuytten, **certify that as the MDEG Administrator for**

Coloplast Corp.,

**that I (initial that you have read and meet the following requirements):**

1. MEN Have a high school diploma or its equivalent;
2. MEN Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MEN Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MEN Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Matthew Nuytten
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6-29-23
Date

| Board Use Only | Date Received: 7.3.23 |
|---|---|

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

An application for a license, or a licensee with a license, to conduct a pharmacy or to operate as a wholesaler shall designate at least one natural person to serve as the representative of the pharmacy or wholesaler. The Board will not issue or renew a license of an applicant or licensee that is required to designate a representative of a pharmacy or wholesaler unless the Board determines that the designated natural person meets the following qualifications per NAC 639.5005 (Pharmacy) or NAC 639.5935 (Wholesaler):

1. Is at least 21 years of age;
2. Has been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.

The designated representative of a pharmacy or a wholesaler:

1. Must be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
2. Must be employed full-time in a managerial level position with the pharmacy or wholesaler;
3. Must be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
4. May serve in this representative capacity for only one pharmacy or wholesaler at a time

A pharmacy or wholesaler that is required to designate a natural person as its representative shall not open or operate the pharmacy or wholesaler unless that representative is actually employed full-time in the operation of the pharmacy or wholesaler and is physically present at the site of the pharmacy or wholesaler during regular working hours, not including sick leave, vacation leave and other authorized absences from work. If the natural person designated as the representative of a pharmacy leaves the employ of the pharmacy or wholesaler, thus leaving the pharmacy or wholesaler without a representative in violation of this section, the pharmacy or wholesaler shall:

1. Immediately cease conducting business until another qualified natural person is approved by the Board to serve as the representative of the pharmacy or wholesaler; and
2. Not later than 48 hours after that person leaves its employ, notify the Board that the person designated as the representative of the pharmacy or wholesaler has left the employ of the pharmacy or wholesaler.

Before a pharmacy or wholesaler, that is in violation of NAC 639.5005 (Pharmacy) or NAC 639.5935 (Wholesaler) because the natural person designated as the representative of the pharmacy or wholesaler left the employ of the pharmacy or wholesaler, may continue conducting business:

1. The pharmacy or wholesaler must designate, on a form provided by the Board, a new natural person to serve as the representative of the pharmacy; and
2. The Board must approve the natural person so designated.

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

**Section 1: Pharmacy/Wholesaler Information**

Name of Pharmacy/Wholesaler Coloplast Corp.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 1940 Commerce Drive

City North Mankato State MN Zip 56003

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 507-870-4056 Website https://www.coloplast.us/

Licensing Company Email N/A

**Section 2: Personal Information**

First Matthew Middle Eric Last Nuytten

Alias(es, nicknames, name changes, etc.) Matt

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted]222nd St

City Lake Crystal State MN Zip 56055

Telephone [redacted] Email usmen@coloplast.com

Are you a citizen of the United States? ■ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✓ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Central Lakes College | | 09/94 - 05/97 | |
| **Address** | **City** | **State** | **Zip** |
| 501 W College Drive | Staples | MN | 56479 |
| Diploma/Degree obtained, if any | | | |
| Degree in Robotics and Automated Systems | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| St. Mary's School | | 9/81 - 05/94 | |
| **Address** | **City** | **State** | **Zip** |
| 104 Saint Mary's Street NW | Sleepy Eye | MN | 56085 |
| Diploma/Degree obtained, if any | | | |
| High School Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 06/20-Current | [redacted]222nd St. | Lake Crystal | MN | 56055 |
| 06/03-06/20 | [redacted]Charlotte Dr. | Lake Crystal | MN | 56055 |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| | | | |
|---|---|---|---|
| Business Name: Coloplast Corp. | | | From - To (MM/YY – MM/YY): 04/03-Current |
| Business Address: 1940 Commerce Drive | City: North Mankato | State: MN | Zip: 56003 |
| Phone: 507-870-4056 | Title: Director, Manufacturing Mankato | | Number of Employed Hours: 41,920 |
| Description of Duties: Responsible for all manufacturing and supply chain operations, quality and R&D. | | | |

| | | | |
|---|---|---|---|
| Business Name | | | From - To (MM/YY – MM/YY) |
| Business Address | City | State | Zip |
| Phone | Title | | Number of Employed Hours |
| Description of Duties | | | |

| | | | |
|---|---|---|---|
| Business Name | | | From - To (MM/YY – MM/YY) |
| Business Address | City | State | Zip |
| Phone | Title | | Number of Employed Hours |
| Description of Duties | | | |

| | | | |
|---|---|---|---|
| Business Name | | | From - To (MM/YY – MM/YY) |
| Business Address | City | State | Zip |
| Phone | Title | | Number of Employed Hours |
| Description of Duties | | | |

| | | | |
|---|---|---|---|
| Business Name | | | From - To (MM/YY – MM/YY) |
| Business Address | City | State | Zip |
| Phone | Title | | Number of Employed Hours |
| Description of Duties | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✓ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✓ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✓ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✓ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| Reason/Charge | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| Name of Business/Industry/Entity | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

6-29-23
Date

I, Matthew Nuytten, **certify that as the designated representative for**

Coloplast Corp.,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. MEN I am at least 21 years of age;
3. MEN I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MEN I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MEN I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MEN I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MEN I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Matthew Nuytten

Print Name (First, Last)

Matthew Nuytten

Original Signature (electronic, copies or stamps not accepted)

6-29-23

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Matthew Nuytten

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6-29-23

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Minnesota, ss. County of Nicollet

I, Matthew Nuytten, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

6-29-23

**Date**

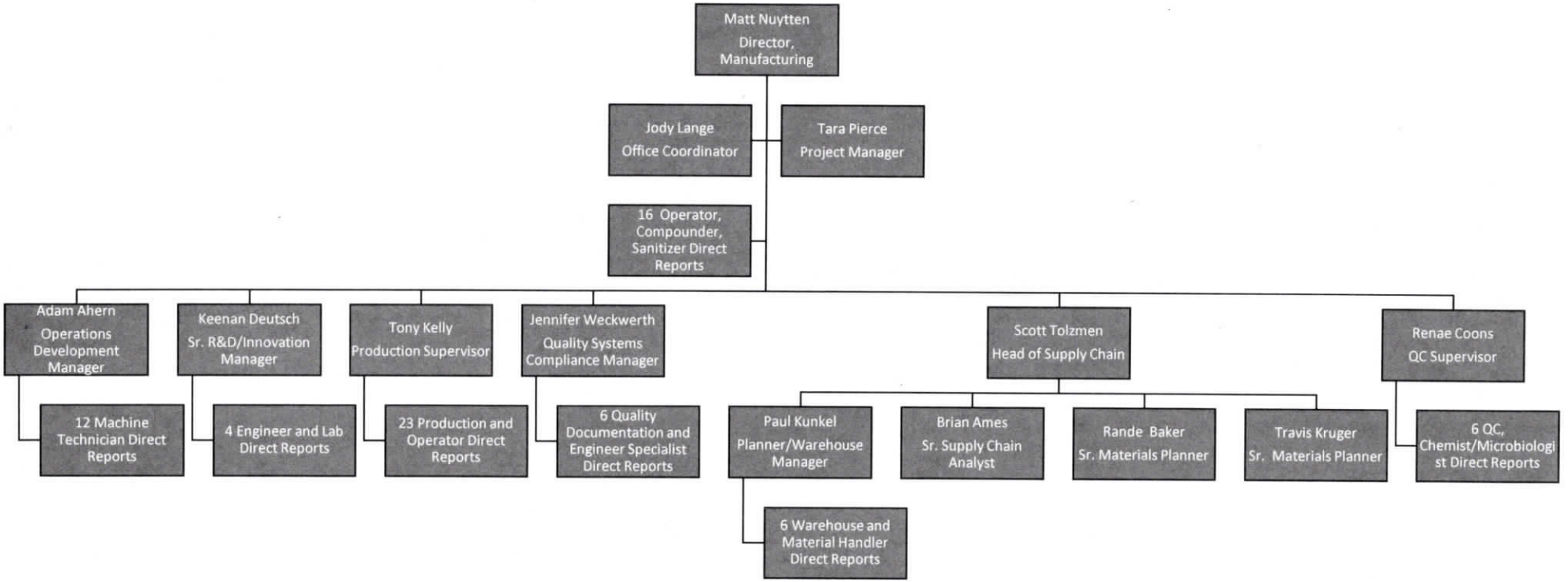
Subscribed and Sworn to before me this 29th day of June.

**Notary Public Signature**

ERIC E CHARTIER
NOTARY PUBLIC - MINNESOTA
MY COMMISSION EXPIRES 01/31/28

**(Seal)**

Employee list



Coloplast

Executive Secretary Dave Wuest
Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

June 30, 2023

Aaron Rodriquez
Senior Legal Counsel, North America
Mobile: 612-889-0672
Mail: usarodr@coloplast.com

Coloplast Corp
1601 West River Road North
Minneapolis, MN 55411
United States

Tel: 612.372.7400
Toll Free Number:
1.800.788.0293
www.coloplast.us

**RE: Coloplast Corp. Wholesaler Application**

To Whom It May Concern:

By this letter, Coloplast Corp. is requesting a temporary wholesaler license for the Coloplast Corp. facility listed below. We are making this request at the same time as we are providing to the Nevada State Board of Pharmacy (BOP) our wholesaler application as discussed on a June 6, 2023 teleconference with me, Tara Farrington and from the BOP, Mr. Zunino, Mr. Wuest and Mr. Cedars. At the conclusion of that call, you sent me an email indicating that I should submit this request for Temporary Licensure on Coloplast letterhead and addressed to you. It is my understanding that, if approved, BOP staff will issue the "temp" license valid until the board meeting date which will be assigned to this application.

This request for temporary licensure is made for Coloplast Corp. (Coloplast) at this facility:

1940 Commerce Drive
North Mankato, MN 56003

Sincerely,

Aaron Rodriquez
Senior Legal Counsel, North America

# Nevada State Board of Pharmacy

985 Damonte Ranch Parkway, Suite 206 • Reno, NV 89521
(775) 850-1440 • FAX (775) 850-1444
Web Page: bop.nv.gov


March 22, 2023

Via Certified Mail and E-Mail (ukms@coloplast.com)

Coloplast Corp.
1601 West River Road
Minneapolis, MN 55411
Attn: Katy Herman, North American Compliance Manager

**CEASE-AND-DESIST and CITATION-AND-FINE ORDER: Case No. 23-072-O**
**Unlicensed Wholesaling Activity in Nevada**

Dear Ms. Herman:

The Nevada State Board of Pharmacy (Board) has determined that Coloplast Corp., a Minnesota-based wholesaler of medical devices and/or equipment, has been distributing its products into Nevada without a license as required by Nevada Revised Statutes (NRS) 639.233. Accordingly, pursuant to NRS 639.2895, you are hereby ordered to immediately **CEASE and DESIST** distributing into Nevada any such products that are restricted by federal law to sale by or on the order of a physician. Additionally, this notice shall serve as a **CITATION** pursuant to NRS 639.2895(2) for the unlicensed wholesaling of medical devices, equipment, and/or gases. Pursuant to NRS 639.2895(3), the Board has assessed an administrative fine against Coloplast Corp. in the amount of five thousand dollars ($5,000.00).

You must pay this administrative fine within 30 days of receipt of this citation, or otherwise contact Board staff to request an alternative payment plan. Payment must be by *cashier's check*, *certified check* or *money order* made payable to "State of Nevada, Office of the Treasurer," to be received at the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

You have the right to appeal this citation by submitting a written request for a hearing to the Board at the Board's Reno office no later than 30 days after receipt of this notice. *See* NRS 639.2895(2). Please be aware that the forgoing does not preclude the filing of administrative or criminal charges if deemed appropriate based upon evidence not currently available to the Board. If you have any questions, please do not hesitate to contact me at 775-850-1440 or zunino@pharmacy.nv.gov.

Sincerely,

/s/ Gregory L. Zunino
Gregory L. Zunino
Senior General Counsel

9171 9690 0935 0279 2906 80

# 4J

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

**Non-Refundable $1,000 Fee**

Rev (08/17/2022)

| **Where is the facility located?** | | ☐ Nevada ☒ Out-of-State |
|---|---|---|
| **Type of Application (check applicable box)** | | **Wholesaler Business Type (check applicable box)** |
| ☐ New Wholesaler<br>☐ Ownership Change*<br>☒ Name Change* (and address - See Attachment A)<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH 03014 | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: Corium, LLC

Physical Address: 11 Farnsworth Street, 4th Floor

City: Boston State: MA Zip: 02210

Mailing Address (if different from physical address): Same as physical address.

City: State: Zip:

Telephone: 617-752-3363 Website: www.Corium.com

Name of Designated Representative (DR): Ivan E. Tosques

Licensing Company Email: itosques@coriumintl.com DR Email: itosques@coriumintl.com

| **Entities the Wholesaler will Serve (✓ all applicable)** | **Products to be Handled or Wholesaled (✓ all applicable)** | **Type of Wholesaling (✓ all applicable)** |
|---|---|---|
| ☐ Pharmacies | ☒ Dangerous Drugs | ☐ Manufacturer |
| ☐ Practitioners | ☒ Controlled Substances | ☐ Repacker |
| ☐ Hospitals | ☐ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ☐ Wholesalers | ☐ Others: | ☐ Warehouse |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ☒ Others: Distributors | | ☒ Others: Virtual Manufacturer |

| **Section 2: History of Company** | **Yes** | **No** |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | X |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | X |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | X |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | X |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | X |

N/A

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| | | | | |
| Reason/Charge | | | | |
| | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| | | | | |
| Name of Business/Industry/Entity | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

Date

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: See Attachment H

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

**Section 4: Publicly Traded Corporation**

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: Delaware

Parent Company (if any): Gurnet Holding Company

Corporation/Organization Name: Corium, LLC

Mailing Address: 11 Farnsworth Street, 4th Floor

City: Boston State: MA Zip: 02210

Telephone: 617-752-3363 Email: itosques@coriumintl.com

Contact Person Name: Ivan Tosques

**Section 6: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

**Section 7: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | X |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: Cabler 605038 | X | |
| 1. Copy of FDA registration<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** | | ✓ | | |
| • **List of all partners and their percent ownership.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Corium, LLC

Facility Name

Ivan Tosques

Print Name of Authorized Person Submitting Application

Ivan Tosques

Original signature of Authorized Person (copies or stamps not accepted)

May 25, 2023

Date

| Board Use Only | Date Received: 7/3/23 | Amount: 1000-CK-890 |
|---|---|---|

**Attachment A**

**Regarding the Changes**

Effective immediately, Corium, Inc. (Nevada license #: WH03014) will change its name to Corium, LLC and move from 4558 50th Street SE, Grand Rapids, MI 49512 to 11 Farnsworth Street, 4th Floor, Boston, MA 02210. Please note that the new facility will function as a virtual manufacturer.

## Attachment B

## FDA Registration and Product List

Enclosed is a list of products including complete NDC numbers. **Please note that the labeler name change (from Corium, Inc. to Corium, LLC) for these products is currently pending with the FDA.**

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

# National Drug Code Directory

Current through December 16, 2022

**You have searched Finished drug products**

**Search Results:** *'Corium, Inc.'*

Back to Search Page () | Search Again ()

CSV Excel

**Display** 50 **records per page** **Search for text in the table:**

| Proprietary Name | NDC Package Code | Strength | Dosage Form | Route | Appl. No. | Labeler Name | Product NDC | Nonproprietary Name | Substance Name | Product Type Name | Start Marketing Date | End Marke Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + Adlarity | 65038-055-03 | 5 mg/1 | PATCH | TRANSDERMAL | NDA212304 | Corium, Inc. | 65038-055 | Donepezil Hydrochloride | DONEPEZIL HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG | 03/11/2022 | N/A |
| + Adlarity | 65038-055-07 | 5 mg/1 | PATCH | TRANSDERMAL | NDA212304 | Corium, Inc. | 65038-055 | Donepezil Hydrochloride | DONEPEZIL HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG | 03/11/2022 | N/A |
| + Adlarity | 65038-056-03 | 10 mg/1 | PATCH | TRANSDERMAL | NDA212304 | Corium, Inc. | 65038-056 | Donepezil Hydrochloride | DONEPEZIL HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG | 03/11/2022 | N/A |
| + Adlarity | 65038-056-07 | 10 mg/1 | PATCH | TRANSDERMAL | NDA212304 | Corium, Inc. | 65038-056 | Donepezil Hydrochloride | DONEPEZIL HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG | 03/11/2022 | N/A |
| + Adlarity | 65038-055-01 | 5 mg/1 | PATCH | TRANSDERMAL | NDA212304 | Corium, Inc. | 65038-055 | Donepezil Hydrochloride | DONEPEZIL HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG | 09/07/2022 | N/A |
| + Adlarity | 65038-055-10 | 5 mg/1 | PATCH | TRANSDERMAL | NDA212304 | Corium, Inc. | 65038-055 | Donepezil Hydrochloride | DONEPEZIL HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG | 09/07/2022 | N/A |
| + Adlarity | 65038-056-01 | 10 mg/1 | PATCH | TRANSDERMAL | NDA212304 | Corium, Inc. | 65038-056 | Donepezil Hydrochloride | DONEPEZIL HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG | 09/07/2022 | N/A |
| + Adlarity | 65038-056-10 | 10 mg/1 | PATCH | TRANSDERMAL | NDA212304 | Corium, Inc. | 65038-056 | Donepezil Hydrochloride | DONEPEZIL HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG | 09/07/2022 | N/A |

Showing 1 to 8 of 8 entries Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)

See also: Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Top (https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm)

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

# National Drug Code Directory

Current through December 21, 2022

**You have searched Finished drug products**

**Search Results**: *'Azstarys'*

Back to Search Page () | Search Again ()

CSV Excel

**Display** 50 **records per page** **Search for text in the table:**

| Proprietary Name | NDC Package Code | Strength | Dosage Form | Route | Appl. No. | Labeler Name | Product NDC | Nonproprietary Name | Substance Name | Product Type Name | Start Marketing Date |
|---|---|---|---|---|---|---|---|---|---|---|---|
| + AZSTARYS | 65038-286-99 | 5.2 mg/1, 26.1 mg/1 | CAPSULE | ORAL | NDA212994 | Corium, Inc | 65038-286 | Serdexmethylphenidate and Dexmethylphenidate | DEXMETHYLPHENIDATE HYDROCHLORIDE; SERDEXMETHYLPHENIDATE CHLORIDE | HUMAN PRESCRIPTION DRUG | 07/16/2021 |
| + AZSTARYS | 65038-429-99 | 7.8 mg/1, 39.2 mg/1 | CAPSULE | ORAL | NDA212994 | Corium, Inc | 65038-429 | Serdexmethylphenidate and Dexmethylphenidate | DEXMETHYLPHENIDATE HYDROCHLORIDE; SERDEXMETHYLPHENIDATE CHLORIDE | HUMAN PRESCRIPTION DRUG | 07/16/2021 |
| + AZSTARYS | 65038-561-99 | 10.4 mg/1, 52.3 mg/1 | CAPSULE | ORAL | NDA212994 | Corium, Inc | 65038-561 | Serdexmethylphenidate and Dexmethylphenidate | DEXMETHYLPHENIDATE HYDROCHLORIDE; SERDEXMETHYLPHENIDATE CHLORIDE | HUMAN PRESCRIPTION DRUG | 07/16/2021 |

Showing 1 to 3 of 3 entries Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)

See also: Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Top (https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm)

**Attachment C**

**LLC Information**

Corium, LLC
(a wholly-owned subsidiary of Gurnet Holding Company)

Perry Sternberg
*CEO/President*

Steven Gersten
*Chief Legal & Compliance Officer/Secretary*

Bimal Shah
*CFO/Treasurer*

**Attachment D**

**Delaware Certificate of Good Standing**

Please note that the enclosed certificate lists the former company name, Corium, Inc. Formal name change documentation from the state of formation is additionally enclosed.

# Delaware

The First State



I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF CONVERSION OF A DELAWARE CORPORATION UNDER THE NAME OF "CORIUM, INC." TO A DELAWARE LIMITED LIABILITY COMPANY, CHANGING ITS NAME FROM "CORIUM, INC." TO "CORIUM, LLC", FILED IN THIS OFFICE ON THE FOURTEENTH DAY OF OCTOBER, A.D. 2022, AT 11:18 O`CLOCK A.M.

Jeffrey W. Bullock, Secretary of State

3496754 8100V
SR# 20223772556

Authentication: 204624513
Date: 10-14-22

You may verify this certificate online at corp.delaware.gov/authver.shtml

State of Delaware
Secretary of State
Division of Corporations
Delivered 11:18 AM 10/14/2022
FILED 11:18 AM 10/14/2022
SR 20223772556 - File Number 3496754

# CERTIFICATE OF CONVERSION
# OF
# CORIUM, INC.
## (a Delaware corporation)

## INTO

# CORIUM, LLC
## (a Delaware limited liability company)

Corium, Inc., a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware, does hereby certify, that:

FIRST: Corium, Inc. was originally incorporated under the laws of the State of Delaware on February 28, 2002 under the name Corium International, Inc.

SECOND: The name of the corporation immediately prior to filing this Certificate is "Corium, Inc."

THIRD: That Corium, Inc. does now wish to convert from a corporation to a limited liability company pursuant to Section 266 of the Delaware General Corporation Law, as amended, and Section 18-214 of the Delaware Limited Liability Company Act, as amended, to be named "Corium, LLC", as set forth in the Certificate of Formation, filed contemporaneously herewith.

FOURTH: The conversion of Corium, Inc. to Corium, LLC has been approved by the board of directors and the stockholders of Corium, Inc. in accordance with Section 266 of the Delaware General Corporation Law, as amended.

*(Signature Page Follows)*

IN WITNESS WHEREOF, Corium, Inc. has caused this Certificate of Conversion to be executed by its duly appointed officer this 14th day of October 2022.

Perry Sternberg

Name: Perry Sternberg
Title: President and Chief Executive Officer

## Attachment H

## Nature of Business

Corium, LLC (Corium) is a virtual manufacturer of prescription drugs and controlled substances located in Massachusetts. Corium will utilize third parties to manufacture and distribute its products. At no time will this facility handle, store, produce, or distribute any products. **Because the facility will not handle product, DEA registration is not required.** The information for each of Corium's third parties is provided below.

**Third party distributor:**

Prasco LLC
6125 Commerce Court
Mason, OH 45040
Contact: Sarah Leach, VP Strategic Commercialization
S.Leach@prasco.com
513-204-1390

**Contract manufacturers:**

Corium Pharma Solutions, Inc.
4558 50th Street, SE
Grand Rapids, MI 49512
FDA registration: 3003693105
Contact: Duane Gibson
Telephone #: 616-656-4563

Catalent Greenville, Inc.
1240 Sugg Pkwy
Greenville, NC 27834
FDA registration: 3000209735
Contact: Chuck Walker, Head of Quality Assurance
Telephone #: 252-707-6310

## Attachment E

## Resident State License

Enclosed is a copy of the resident state (Massachusetts) license. **Please note that prescription drugs are classified as a schedule VI controlled substance in the State of Massachusetts.**

An official website of the Commonwealth of Massachusetts Here's how you know

# Mass.gov Office of Health and Human Services (EOHHS) License Verification Site



## License Information

| | |
|---|---|
| **License Type:** | Virtual Drug Manufacturer or Virtual Drug Distributor Controlled Substance Registration |
| **License Number:** | MA0001115 |
| **Status:** | Current |
| **Organization Name:** | CORIUM, LLC |
| **Expiration Date:** | September 22, 2024 |
| **Address:** | 11 FARNSWORTH STREET 4TH FLOOR BOSTON, MA 02210 |

## Compliance Actions/Fines

There are no public compliance actions or fines against this license/registration record.

**Disclaimer:** The information contained in this website ("website content") is made available as a public service by the Massachusetts Department of Public Health (the Department). The Department considers this information to constitute primary source verification. Click here for full disclaimer.

<< Back to Search Page

## How To Get Help:

### Mass.gov Resources

eLicensing User Guide
Bureau of Health Professions Licensure
Office of Local and Regional Health
Department of Public Health

Phone:(800) 414-0168
TTY Line: (617) 973-0988

### BHPL eLicensing Support Resources

Online:eLicensing Support Request Form
Email:dph.elicensing_support@mass.gov

**DO NOT provide your Social Security Number** or **Date of Birth** when contacting the eLicensing Support Desk online or by email

Did you find what you were looking for on this webpage? Please provide your feedback here.

Powered By JD Software ArcHealth

## CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7

| NUMBER | ISSUED | EXPIRES | TYPE |
|---|---|---|---|
| MA0001115 | 09/22/2022 | 09/22/2023 | Virtual Drug Manufacturers |

ISSUED TO

CORIUM, LLC
11 FARNSWORTH STREET
4TH FLOOR
BOSTON, MA 02210
ATTN: STEVEN N GERSTEN CHIEF LEGAL OFFICE

**NEW**


## CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7

| NUMBER | ISSUED | EXPIRES | TYPE |
|---|---|---|---|
| MA0001115 | 09/22/2022 | 09/22/2023 | Virtual Drug Manufacturers |

ISSUED TO

CORIUM, LLC
11 FARNSWORTH STREET
4TH FLOOR
BOSTON, MA 02210
ATTN: STEVEN N GERSTEN CHIEF LEGAL OFFICE

**NEW**

## CONTROLLED SUBSTANCES REGISTRATIONS

In Accordance with Massachusetts General Laws Chapter 94C, Section 7

| NUMBER | ISSUED | EXPIRES | TYPE |
|---|---|---|---|
| MA0001115 | 09/22/2022 | 09/22/2023 | Virtual Drug Manufacturers |

ISSUED TO CORIUM, LLC
11 FARNSWORTH STREET
4TH FLOOR
BOSTON, MA 02210
ATTN: STEVEN N GERSTEN CHIEF LEGAL OFFICE

NEW

**NEVADA STATE BOARD OF PHARMACY**
**985 Damonte Ranch Pkwy Suite 206**
**Reno, NV 89521**
**(775) 850-1440**
**Fax: (775) 850-1444**

# PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 57BSBII2422

Application/License No. _____

Corium, LLC (f/k/a Corium, Inc.), doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
11 Farnsworth Street, 4th Floor, Boston, MA 02210, as
Address of Applicant/Principal
PRINCIPAL, and Hartford Fire Insurance Company, a
Surety Company
corporation organized under the laws of the state of Connecticut
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
One Hartford Plaza, Hartford, CT 06155-0001 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 28, 2022.
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 28th day of October, 20 22.

APPLICANT/PRINCIPAL

COMPANY
Corium, LLC (f/k/a Corium, Inc.)

Authorized Representative

SURETY

Hartford Fire Insurance Company

Surety Company's Representative

Erin Bautista, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Not Applicable
Nevada Resident Agent

# ACKNOWLEDGMENT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Santa Clara )

On OCT 2 8 2022 before me, Jean L. Neu, Notary Public
(insert name and title of the officer)

personally appeared Erin Bautista,
who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/~~are~~ subscribed to the within instrument and acknowledged to me that ~~he~~/she/~~they~~ executed the same in ~~his~~/her/~~their~~ authorized capacity(~~ies~~), and that by ~~his~~/her/~~their~~ signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

JEAN L. NEU
Notary Public - California
Santa Clara County
Commission # 2392720
My Comm. Expires Mar 1, 2026

Signature _____ (Seal)

# POWER OF ATTORNEY

THE HARTFORD
BOND, T-12
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: 888-266-3488 or fax: 860-757-5835



**KNOW ALL PERSONS BY THESE PRESENTS THAT:**

**Agency Name:** ABD INSURANCE AND FINANCIAL SVCS
**Agency Code:** 57-141591

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [X] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [X] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois**, a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast**, a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut, (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint, ***up to the amount of*** Unlimited :

Angelina A. Campano, Debra Ann Perry, Eric Alburger, Erin Bautista, Steve Leveroni, Bryan D. Martin, Jean L. Neu of SAN MATEO, California

their true and lawful Attorney(s)-in-Fact, each in their separate capacity if more than one is named above, to sign its name as surety(ies) only as delineated above by ☒, and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

**In Witness Whereof,** and as authorized by a Resolution of the Board of Directors of the Companies on May 6, 2015 the Companies have caused these presents to be signed by its Senior Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

John Gray, Assistant Secretary

M. Ross Fisher, Senior Vice President

STATE OF CONNECTICUT }
COUNTY OF HARTFORD } ss. Hartford

On this 5th day of January, 2018, before me personally came M. Ross Fisher, to me known, who being by me duly sworn, did depose and say: that he resides in the County of Hartford, State of Connecticut; that he is the Senior Vice President of the Companies, the corporations described in and which executed the above instrument; that he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that he signed his name thereto by like authority.

Kathleen T. Maynard
Notary Public
My Commission Expires July 31, 2021

**CERTIFICATE**

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of October 28, 2022

Signed and sealed at the City of Hartford.

Kevin Heckman, Assistant Vice President

## Attachment I

## Designated Representative Form

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

**Section 1: Pharmacy/Wholesaler Information**

Name of Pharmacy/Wholesaler: Corium, LLC

Pharmacy/Wholesaler License # (if applicable): WH03014 (currently licensed as Corium, Inc.)

Physical Address: 11 Farnsworth Street, 4th Floor

City: Boston State: MA Zip: 02210

Mailing Address (if different from physical address): Same as physical address.

City: State: Zip:

Telephone: 617-752-3363 Website: www.Corium.com

Licensing Company Email: itosques@coriumintl.com

**Section 2: Personal Information**

First: Ivan Middle: Edward Last: Tosques

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: 11 Farnsworth Street, 4th Floor

City: Boston State: MA Zip: 02210

Telephone: [redacted] Email: itosques@coriumintl.com

Are you a citizen of the United States? ■ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | X |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A | N/A | N/A |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| University of California at Berkeley | | | 1984 - 1988 | |
| Address | | City | State | Zip |
| One South Hall Road | | Berkeley | CA | 94720 |
| Diploma/Degree obtained, if any | | | | |
| | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| Lowell High School | | | 1980 - 1984 | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| General diploma | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |
| School Name | | | From - To (MM/YY – MM/YY | |
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 08/15 - Present | [redacted]Bruce Road | Winchester | MA | 01890 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| 06/07 - 07/15 | [redacted]Galer Drive | Newtown Square | PA | 19073 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Corium, LLC | | | 12/19 - Present |
| **Business Address** | **City** | **State** | **Zip** |
| 11 Farnsworth Street, 4th Floor | Boston | MA | 02210 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| 617-752-3363 | VP, Market Access | 40 hours/week | |
| **Description of Duties** | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Skysis Consulting | | | 05/19 - 12/19 |
| **Business Address** | **City** | **State** | **Zip** |
| 11445 E. Via Linda, Suite 2621 | Scottsdale | AZ | 85259 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | . Independent Consultant | 40 hours/week | |
| **Description of Duties** | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Takeda | | | 01/19 - 04/19 |
| **Business Address** | **City** | **State** | **Zip** |
| 300 Shire Way | Lexington | MA | 02421 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | 40 hours/week | |
| **Description of Duties** | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Shire Pharmaceuticals | | | 02/12 – 12/18 |
| **Business Address** | **City** | **State** | **Zip** |
| 300 Shire Way | Lexington | MA | 02421 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | Head, US Government Market Access | 40 hours/week | |
| **Description of Duties** | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Shire Pharmaceuticals | | | 02/11 - 02/12 |
| **Business Address** | **City** | **State** | **Zip** |
| 300 Shire Way | Lexington | MA | 02421 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | Vice President ~~Senior Director~~, Contracts, Pricing & Reporting | 40 hours/week | |
| **Description of Duties** | | | |

Continue on next page if additional space is needed.

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Shire Pharmaceuticals | | 08/06 - 02/11 | |
| Business Address | City | State | Zip |
| 300 Shire Way | Lexington | MA | 02421 |
| Phone | Title | Number of Employed Hours | |
| | Senior Director, Contracts, Pricing & Reporting | 40 hours/week | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Ernst & Young LLP | | 06/04 – 10/05 | |
| Business Address | City | State | Zip |
| 2005 Market Street, Suite 700 | Philadelphia | PA | 19103 |
| Phone | Title | Number of Employed Hours | |
| | Manager | 40 hours/week | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Computer Sciences Corporation | | 09/99 – 06/04 | |
| Business Address | City | State | Zip |
| 1160 Swedesford Road | Berwyn | PA | 19312 |
| Phone | Title | Number of Employed Hours | |
| | Senior Consultant | 40 hours/week | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Business Address | City | State | Zip |
| | | | |
| Phone | Title | Number of Employed Hours | |
| | | | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Business Address | City | State | Zip |
| | | | |
| Phone | Title | Number of Employed Hours | |
| | | | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

May 25, 2023
Date

I, Ivan Tosques, **certify that as the designated representative for**

Corium, LLC,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. ✓ I am at least 21 years of age;
3. ✓ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ✓ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ✓ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ✓ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ✓ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Ivan Tosques

Print Name (First, Last)

Ivan Tosques

Original Signature (electronic, copies or stamps not accepted)

May 25, 2023

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Ivan Tosques

Print Name (First, Last)

Ivan Tosques

Original Signature (electronic, copies or stamps not accepted)

May 25, 2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Massachusetts, ss. County of Middlesex

I, Laurie Poland, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Ivan Tosques

**Original Signature**

May 25, 2023

**Date**

Subscribed and Sworn to before me this 25 day of May 2023.

Laurie Poland

**Notary Public Signature**

**(Seal)**

LAURIE POLAND
NOTARY PUBLIC
Commonwealth of Massachusetts
My Commission Expires
August 9, 2024

**CORIUM LLC BOSTON SITE EMPLOYEE LIST**

February 8, 2023

Aimee Scott <Aimee.Scott@coriumintl.com>; AJ Balkema <AJ.BALKEMA@coriumintl.com>; Amulya Nandakumar <Amulya.Nandakumar@coriumintl.com>; Amy Campbell <AMY.CAMPBELL@coriumintl.com>; Amy Clements <Amy.Clements@coriumintl.com>; Ben Newman <bnewman@coriumintl.com>; Bimal Shah <Bimal.Shah@coriumintl.com>; Blythe Buchanan <Blythe.Buchanan@coriumintl.com>; Breanna Waelter <Breanna.Waelter@coriumintl.com>; Brett Smith <Brett.Smith@coriumintl.com>; Brian Mayville <Brian.Mayville@coriumintl.com>; Brittany Rivard <Brittany.Rivard@coriumintl.com>; Brittany Williams <Brittany.Williams@coriumintl.com>; Callen Breen <Callen.Breen@coriumintl.com>; Carmen Hinton <Carmen.Hinton@coriumintl.com>; Catie Tokarz <catie.tokarz@coriumintl.com>; Charles Oh <coh@coriumintl.com>; Chelsea Panora <cpanora@coriumintl.com>; Chris Trotter <ctrotter@coriumintl.com>; Christopher Risavi <Christopher.Risavi@coriumintl.com>; Cort Morrison <Cort.Morrison@coriumintl.com>; Dan Arsulowicz <danaz@coriumintl.com>; Daniel Zhao <Daniel.Zhao@coriumintl.com>; Dawn Scheibel <Dawn.Scheibel@coriumintl.com>; Denise O'Neill <dkimoneill@coriumintl.com>; Edward DePaz <edepaz@coriumintl.com>; Elizabeth Arpino <Elizabeth.Arpino@coriumintl.com>; Ellen Contois <Ellen.Contois@coriumintl.com>; Emily Allard <eallard@coriumintl.com>; Emily Kerin <Emily.Kerin@coriumintl.com>; Erik Frazier <efrazier@coriumintl.com>; Fred Peterson <Matthew.Peterson@coriumintl.com>; Ivan Tosques <itosques@coriumintl.com>; Jamie Spaeth <jspaeth@coriumintl.com>; Jason Evans <Jason.Evans@coriumintl.com>; Jason Falso <Jason.Falso@coriumintl.com>; Jason Jan <Jason.Jan@coriumintl.com>; Jeff Gaffey <Jeffg@coriumintl.com>; Jennifer Graham <jgraham@coriumintl.com>; Jennifer Murawski <Jennifer.Murawski@coriumintl.com>; Jeremy Smoldon <Jeremy.Smoldon@coriumintl.com>; Jill Cafaro <Jill.Cafaro@coriumintl.com>; Jill Riley <Jill.Riley@coriumintl.com>; Jill Schmidt <Jill.Schmidt@coriumintl.com>; Joel Stouten <joels@coriumintl.com>; John Neeley <jneeley@coriumintl.com>; John Price <jprice@coriumintl.com>; John Wiles <JOHN.WILES@coriumintl.com>; Josephine Pedalino <josephine.pedalino@coriumintl.com>; Julio Rivera <Julio.Rivera@coriumintl.com>; Justin Bessette <jbessette@coriumintl.com>; Karan Shah <kshah@coriumintl.com>; Kasper Veje <Kasper.Veje@coriumintl.com>; Kathy Francini <kfrancini@coriumintl.com>; Keith Fine <Keith.Fine@coriumintl.com>; Kevin Cowles <kcowles@coriumintl.com>; Kevin Shea <Kevin.Shea@coriumintl.com>; Kim Dobbins <Kim.Dobbins@coriumintl.com>; Kimberly Lundry <Kim.Lundry@coriumintl.com>; Kyle Crossley <Kyle.Crossley@coriumintl.com>; Laura Hynes <Laura.Hynes@coriumintl.com>; Laura Scott <lscott@coriumintl.com>; Lauren Hudson <lhudson@coriumintl.com>; Lee Pan <lpan@coriumintl.com>; Lee Ramsden <Lee.Ramsden@coriumintl.com>; Lindsey Reichelt <lreichelt@coriumintl.com>; Liz McClure <elizabeth.mcclure@coriumintl.com>; Lyndsay Shea <Lyndsay.Shea@coriumintl.com>; Magdalena Clovis <magdalena.clovis@coriumintl.com>; Matt Daniels <mdaniels@coriumintl.com>; Matt Hand <Matthew.Hand@coriumintl.com>; Maxwell Petersen <Maxwell.Petersen@coriumintl.com>; Meg Corliss <ycorliss@coriumintl.com>; Melissa Peros <Melissa.Peros@coriumintl.com>; Michael Bradley <Michael.Bradley@coriumintl.com>; Michael Oh <Michael.Oh@coriuminternational.onmicrosoft.com>; Nicholas Pettry <Nick.Pettry@coriumintl.com>; Nick Smith <Nicholas.Smith@coriumintl.com>; Patrick Ferguson <Patrick.Ferguson@coriumintl.com>; Patrick Sullivan <patrick.sullivan@coriumintl.com>; Perry Sternberg <psternberg@coriumintl.com>;

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# 4K

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

## Non-Refundable $1,000 Fee

Rev (08/17/2022)

| Where is the facility located? | | ☐ Nevada ☒ Out-of-State |
|---|---|---|
| **Type of Application (check applicable box)** | | **Wholesaler Business Type (check applicable box)** |
| ☒ New Wholesaler<br>☐ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH _____ | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: Cranbury Pharmaceuticals, LLC

Physical Address: 2031 US Highway 130, Suite F

City: Monmouth Junction State: NJ Zip: 08852

Mailing Address (if different from physical address): c/o State License Servicing, 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: cranburyPharma.com

Name of Designated Representative (DR): Janet E Penner

Licensing Company Email: CPL@slsny.com DR Email: jpenner@trispharma.com

| Entities the Wholesaler will Serve (✓ all applicable) | Products to be Handled or Wholesaled (✓ all applicable) | Type of Wholesaling (✓ all applicable) |
|---|---|---|
| ☐ Pharmacies | ☒ Dangerous Drugs | ☒ Manufacturer - Virtual |
| ☐ Practitioners | ☒ Controlled Substances | ☐ Repacker |
| ☐ Hospitals | ☐ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ☒ Wholesalers | ☐ Others: | ☐ Warehouse |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ☐ Others: | | ☐ Others: |

| Section 2: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | X |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | X |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | X |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | X |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | X |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question #** N/A **. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

N/A

Original Signature (electronic, copies or stamps not accepted)

June 7, 2023
Date

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: Tris Pharma Inc
Address: 2033 Route 130 South, Suite D City: Monmouth Junction State: NJ Zip: 08852

Name: CSPC Ouyi Pharmaceutical CO., LTD
Address: No.88 Yanzi Road, Economic Technology development zone City: Shijiazhuang, 052160 State: China ~~Zip:~~

Name: Indoco Remedies Limited
Address: Goa Plant-II, III, L-32, 33, 34 Verna Industrial Area City: Verna Goa, 403722 State: India ~~Zip:~~

Name: Changzhou Pharmaceutical Factory
Address: No. 518 Laodong East Rd, Changzhou City: Jiangsu Province, 213018 State: China ~~Zip:~~

**Section 4: Publicly Traded Corporation**

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: NJ
Parent Company (if any): Tris Pharma, Inc.
Corporation/Organization Name: Cranbury Pharmaceuticals, LLC
Mailing Address: c/o State License Servicing 1751 State Route 17A, Suite 3
City: Florida State: NY Zip: 10921
Telephone: (845) 544-2482 Email: CPL@slsny.com
Contact Person Name: Christine Cannon

**Section 6: Partnership**

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

**Section 7: Sole Owner**

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | X |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: Labeler Code: 27808 | X | |
| 1. Copy of FDA registration<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** | | ✓ | | |
| • **List of all partners and their percent ownership.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

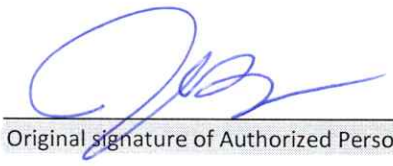
**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Cranbury Pharmaceuticals, LLC

Facility Name

Janet E Penner

Print Name of Authorized Person Submitting Application



Original signature of Authorized Person (copies or stamps not accepted)

June 7, 2023

Date

| Board Use Only | Date Received: 7/5/23 | Amount: 1000-CK-6524 |
|---|---|---|

CRANBURY PHARMACEUTICALS
2031 U.S. Highway 130, Suite F
Monmouth Junction, NJ 08852, USA
Phone: 732-940-2800

To Whom It May Concern:

Cranbury Pharmaceuticals, LLC is a wholly owned subsidiary of Tris Pharma, Inc. As a wholly owned subsidiary, Cranbury Pharmaceuticals, LLC will be selling products under labeler code 27808, which is the labeler code that has been assigned to Tris Pharma, Inc.

Please see the attached communication from the FDA confirming that Cranbury Pharmaceuticals, LLC can share the labeler code with their parent entity.

**From:** CDER Electronic Drug Registration and Listing <EDRLS@fda.hhs.gov>
**Sent:** Thursday, December 1, 2022 7:13 AM
**To:** Norma Cappetti <ncappetti@trispharma.com>
**Cc:** Tris RA <TrisRA@trispharma.com>
**Subject:** <**EXTERNAL**> RE: [EXTERNAL] Labeler Code Question

Ms. Cappetti,

It's best if the information on the labeler code SPL is updated to Cranbury Pharmaceuticals, LLC for more clarity, but if as you mentioned, Cranbury Pharmaceuticals, LLC is a subsidiary of Tris Pharma, Inc. they can indeed share the labeler code.

Regards,
eDRLS Branch

***

**From:** Norma Cappetti <ncappetti@trispharma.com>
**Sent:** Monday, November 28, 2022 10:58 AM
**To:** CDER Electronic Drug Registration and Listing <EDRLS@fda.hhs.gov>
**Cc:** Tris RA <TrisRA@trispharma.com>
**Subject:** [EXTERNAL] Labeler Code Question

Tris Pharma, Inc. ("Tris") was assigned labeler code 27808 and has used this labeler code on generic products manufactured and marketed by Tris since 2013.

In 2023, Tris intends to begin selling its generic products through a wholly owned subsidiary, Cranbury Pharmaceuticals, LLC ("Cranbury"). Tris does not plan to change the labeler code therefore Cranbury will sell the generic products with labeler code 27808.

Sponsorship of most of the ANDAs owned by Tris for generic products that will be sold by Cranbury, will be transferred from Tris to Cranbury.

*Please confirm that it is acceptable to (continue to) label generic products with the 27808 labeler code when they are distributed by Cranbury Pharmaceuticals, LLC.*

Thank you.

*Norma J Cappetti*
*SVP Regulatory Affairs*
*Tris Pharma, Inc*
*Direct: 732-823-4510*

**Disclaimer**
The information contained in this communication from the sender is confidential. It is intended solely for use by the recipient and others authorized to receive it. If you are not the recipient, you are hereby notified that any disclosure, copying, distribution or taking action in relation of the contents of this information is strictly prohibited and may be unlawful.

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

# Drug Establishments Current Registration Site

New Search (default.cfm)

Search Results for **cranbury pharma**

CSVExcel

Filter:

| Firm Name | FDA Establishment Identifier | DUNS | Business Operations | Address | Expiration Date |
|---|---|---|---|---|---|
| Cranbury Pharmaceuticals, Inc. | 3010241920 | 078889499 | RELABEL; | 2031 Route 130, MONMOUTH JUNCTION, New Jersey (NJ) 08852, United States (USA) | 12/31/2023 |

Showing 1 to 1 of 1 entries
Previous1Next
Data Current through: Sunday, Jul 2, 2023

Verified 7.3.23

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

# Cranbury Pharmaceuticals, LLC

**Corporate Address:** 2033 US Highway 130, Suite F, Monmouth Junction , NJ 08852 USA
**FEIN:** 88-3545967
cranburyPharma.com

**Drug Labeler Code:** 27808
**Incorporation State:** NJ
**Incorporation Date:** 7/26/2022

**FACILITY INFORMATION**

| Code | Address | FDA | DEA | DUNS | VAWD | Phone | Fax |
|---|---|---|---|---|---|---|---|
| MON | 2031 US Highway 130<br>Suite F<br>Monmouth Junction, NJ 08852<br>County: Middlesex | | | | No | (732) 940-2800 | |

**FACILITY DESIGNATED REPRESENTATIVES**

| Name | Address | Title | Prescribing Authority | SSN | DOB | Driver's License |
|---|---|---|---|---|---|---|
| Janet E Penner | [redacted]Lehigh Drive<br>Walnutport, PA 18088 | President | | [redacted] | [redacted] | [redacted] |

**OWNERSHIP**

| Name | Address | Title | Percent of Ownership | Prescribing Authority | FEIN/SSN | DOB | Driver's License |
|---|---|---|---|---|---|---|---|
| Tris Pharma, Inc. | 2031 US Highway 130<br>Monmouth Junction, NJ 08852 | N/A | 100 | N/A | [redacted] | N/A | N/A |

**LIST OF OFFICERS**

| Name | Address | Title | Prescribing Authority | SSN | DOB | Driver's License |
|---|---|---|---|---|---|---|
| Jonathan N Provoost | [redacted] Meeker Road<br>Bernardsville , NJ 07924 | General Counsel | | [redacted] | [redacted] | NJ-[redacted] |
| Janet E Penner | [redacted]Lehigh Drive<br>Walnutport, PA 18088 | President | | [redacted] | [redacted] | [redacted] |
| Peter Michael Ciano | [redacted]Harding St<br>Westfield, NJ 07090 | Chief Financial Officer | | [redacted] | [redacted] | NJ-[redacted] |

**3PLS**

| Name | Address | Title | Prescribing Authority | SSN | DOB | Driver's License |
|---|---|---|---|---|---|---|
| RxCrossroads 3PL LLC | 4200 Binion Way, Suite 200<br>Mason, OH 45036 | | | | | |

Company particulars

Good Standing



***STATE OF NEW JERSEY***
***DEPARTMENT OF THE TREASURY***
***DIVISION OF REVENUE AND ENTERPRISE SERVICES***
***SHORT FORM STANDING***

***CRANBURY PHARMACEUTICALS, LLC***
*0600477904*

*I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic Limited Liability Company was registered by this office on July 28, 2022.*

*As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.*

*I further certify that the registered agent and office are:*

*KETAN MEHTA*
*C/O TRIS PHARMA, INC.*
*2031 US HIGHWAY 130*
*MONMOUTH JUNCTION, NJ 08852*

*IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 31st day of May, 2023*

*Elizabeth Maher Muoio*
*State Treasurer*

*Certificate Number : 6143582592*

*Verify this certificate online at*

*https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp*

Mackenzie Winne - All Ope... > 77477

Reply | Add note | Forward | Close | Merge | Delete

Overdue

## RE: [EXTERNAL] Verification of Licensure

DOH-PHFPP reported via email

Add summary

**DOH-PHFPP** reported via email

*18 days ago (Fri, 11 Sep 2020 at 4:44 PM)*

To: "'SLSNYSupport.com'" <help@slsnysupport.com>

Thank you. Due to limited resources, the NJ Department of Health cannot complete license verification forms for other states. Please utilize the online verification system on our webpage: https://nj.gov/health/ceohs/food-drug-safety/medical-device-reg/

**Jennifer Steffee** | Public Health Representative
NJ Department of Health | Public Health & Food Protection
PO Box 369 | 135 E State St | Trenton, NJ 08625
609.913.5150 | http://nj.gov/health/ceohs

Home State (NJ) Letter- No official VOL

Home State (NJ) License Verification



New Jersey Department of Health
P.O. Box 369, Trenton, New Jersey 08625-0369
Drug and Medical Device Certificate of Registration

Information recorded in the system as of 6/27/2023

**Registration Number:** 5006334 **Registered as:** Wholesale

**Name:** CRANBURY PHARMACEUTICALS, LLC

**DBA:**

**Address:** 2031 US HWY 130, STE F, MONMOUTH JUNCTION, NJ 08852

**Original Issue Date:** 06/21/2023 **Expiration Date:** 01/31/2024

**Current Issue Date:** 06/21/2023

**Disciplines:** No

# Registrant Verification For

## RXCROSSROADS 3PL LLC

| | |
|---|---|
| DEA Number: | RR0577241 |
| Expiration Date: | 04/30/2024 |
| Additional Company Info: | |
| Registered Address: | 4200 BINION WAY STE 200 |
| City: | MASON |
| State: | OH |
| Zip Code: | 45036 |
| Business Activity: | DISTRIBUTOR |
| DEA Schedules: | 2 2N 3 3N 4 5 |
| Payment Indicator: | Paid |
| Registration Status: | ACTIVE |
| Date of Verification: | 05/15/2023 |

This Primary Source Verification was obtained from the Drug Enforcement Administration's Controlled Substance Act Registrant Database.

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

## PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 9425960

Application/License No. _____

Cranbury Pharmaceuticals LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 2031 US HWY 130, Monmouth Junction, NJ 08852 (Address of Applicant/Principal), as PRINCIPAL, and Fidelity and Deposit Company of Maryland (Surety Company), a corporation organized under the laws of the state of Illinois (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 3910 Keswick Road, Baltimore, MD 21211 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on March 29, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 29th day of March, 2023.

APPLICANT/PRINCIPAL

COMPANY

Authorized Representative

SURETY

Fidelity and Deposit Company of Maryland

Surety Company's Representative

Robyn Rost, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Karla Luongo

Witness Alexis Miranti

Countersigned by:

Nevada Resident Agent

**ZURICH AMERICAN INSURANCE COMPANY**
**COLONIAL AMERICAN CASUALTY AND SURETY COMPANY**
**FIDELITY AND DEPOSIT COMPANY OF MARYLAND**
**POWER OF ATTORNEY**

KNOW ALL MEN BY THESE PRESENTS: That the ZURICH AMERICAN INSURANCE COMPANY, a corporation of the State of New York, the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, a corporation of the State of Illinois, and the FIDELITY AND DEPOSIT COMPANY OF MARYLAND a corporation of the State of Illinois (herein collectively called the "Companies"), by **Robert D. Murray, Vice President,** in pursuance of authority granted by Article V, Section 8, of the By-Laws of said Companies, which are set forth on the reverse side hereof and are hereby certified to be in full force and effect on the date hereof, do hereby nominate, constitute, and appoint, **Robyn ROST and Raymond GIL, both of Matawan, New Jersey, EACH,** its true and lawful agent and Attorney-in-Fact, to make, execute, seal and deliver, for, and on its behalf as surety, and as its act and deed: **any and all bonds and undertakings,** and the execution of such bonds or undertakings in pursuance of these presents, shall be as binding upon said Companies, as fully and amply, to all intents and purposes, as if they had been duly executed and acknowledged by the regularly elected officers of the ZURICH AMERICAN INSURANCE COMPANY at its office in New York, New York., the regularly elected officers of the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY at its office in Owings Mills, Maryland., and the regularly elected officers of the FIDELITY AND DEPOSIT COMPANY OF MARYLAND at its office in Owings Mills, Maryland., in their own proper persons.

The said Vice President does hereby certify that the extract set forth on the reverse side hereof is a true copy of Article V, Section 8, of the By-Laws of said Companies, and is now in force.

IN WITNESS WHEREOF, the said Vice-President has hereunto subscribed his/her names and affixed the Corporate Seals of the said **ZURICH AMERICAN INSURANCE COMPANY, COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, and FIDELITY AND DEPOSIT COMPANY OF MARYLAND,** this 26th day of September, A.D. 2019.

**ZURICH AMERICAN INSURANCE COMPANY**
**COLONIAL AMERICAN CASUALTY AND SURETY COMPANY**
**FIDELITY AND DEPOSIT COMPANY OF MARYLAND**

*By: Robert D. Murray*
*Vice President*

*By: Dawn E. Brown*
*Secretary*

**State of Maryland**
**County of Baltimore**

On this 26th day of September, 2019, before the subscriber, a Notary Public of the State of Maryland, duly commissioned and qualified, **Robert D. Murray, Vice President and Dawn E. Brown, Secretary** of the Companies, to me personally known to be the individuals and officers described in and who executed the preceding instrument, and acknowledged the execution of same, and being by me duly sworn, deposeth and saith, that he/she is the said officer of the Company aforesaid, and that the seals affixed to the preceding instrument are the Corporate Seals of said Companies, and that the said Corporate Seals and the signature as such officer were duly affixed and subscribed to the said instrument by the authority and direction of the said Corporations.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal the day and year first above written.

Constance A. Dunn, Notary Public
My Commission Expires: July 9, 2023

## EXTRACT FROM BY-LAWS OF THE COMPANIES

"Article V, Section 8, Attorneys-in-Fact. The Chief Executive Officer, the President, or any Executive Vice President or Vice President may, by written instrument under the attested corporate seal, appoint attorneys-in-fact with authority to execute bonds, policies, recognizances, stipulations, undertakings, or other like instruments on behalf of the Company, and may authorize any officer or any such attorney-in-fact to affix the corporate seal thereto; and may with or without cause modify of revoke any such appointment or authority at any time."

## CERTIFICATE

I, the undersigned, Vice President of the ZURICH AMERICAN INSURANCE COMPANY, the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, and the FIDELITY AND DEPOSIT COMPANY OF MARYLAND, do hereby certify that the foregoing Power of Attorney is still in full force and effect on the date of this certificate; and I do further certify that Article V, Section 8, of the By-Laws of the Companies is still in force.

This Power of Attorney and Certificate may be signed by facsimile under and by authority of the following resolution of the Board of Directors of the ZURICH AMERICAN INSURANCE COMPANY at a meeting duly called and held on the 15th day of December 1998.

RESOLVED: "That the signature of the President or a Vice President and the attesting signature of a Secretary or an Assistant Secretary and the Seal of the Company may be affixed by facsimile on any Power of Attorney...Any such Power or any certificate thereof bearing such facsimile signature and seal shall be valid and binding on the Company."

This Power of Attorney and Certificate may be signed by facsimile under and by authority of the following resolution of the Board of Directors of the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY at a meeting duly called and held on the 5th day of May, 1994, and the following resolution of the Board of Directors of the FIDELITY AND DEPOSIT COMPANY OF MARYLAND at a meeting duly called and held on the 10th day of May, 1990.

RESOLVED: "That the facsimile or mechanically reproduced seal of the company and facsimile or mechanically reproduced signature of any Vice-President, Secretary, or Assistant Secretary of the Company, whether made heretofore or hereafter, wherever appearing upon a certified copy of any power of attorney issued by the Company, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

IN TESTIMONY WHEREOF, I have hereunto subscribed my name and affixed the corporate seals of the said Companies, this 29th day of March, 2023.

Brian M. Hodges, Vice President

**TO REPORT A CLAIM WITH REGARD TO A SURETY BOND, PLEASE SUBMIT A COMPLETE DESCRIPTION OF THE CLAIM INCLUDING THE PRINCIPAL ON THE BOND, THE BOND NUMBER, AND YOUR CONTACT INFORMATION TO:**

Zurich Surety Claims
1299 Zurich Way Schaumburg, IL
60196-1056
www.reportsfclaims@zurichna.com
800-626-4577

Bond



# THE FIDELITY AND DEPOSIT COMPANY

OF MARYLAND
1299 Zurich Way Schaumburg, IL 60196

**Statement of Financial Condition**
As Of December 31, 2022

## ASSETS

| | | |
|---|---|---|
| Bonds | | $ 219,365,765 |
| Stocks | | 17,619,752 |
| Cash and Short-Term Investments | | 2,767,685 |
| Reinsurance Recoverable | | 12,309,422 |
| Federal Income Tax Recoverable | | 0 |
| Other Accounts Receivable | | 32,200,768 |
| TOTAL ADMITTED ASSETS | | $ 284,263,392 |

## LIABILITIES, SURPLUS AND OTHER FUNDS

| | | |
|---|---|---|
| Reserve for Taxes and Expenses | | $ 545,031 |
| Ceded Reinsurance Premiums Payable | | 42,850,834 |
| Remittances and Items Unallocated | | 0 |
| Payable to parents, subs and affiliates | | 0 |
| Securities Lending Collateral Liability | | 0 |
| TOTAL LIABILITIES | | $ 43,395,865 |
| Capital Stock, Paid Up | $ 5,000,000 | |
| Surplus | 240,867,527 | |
| Surplus as regards Policyholders | | 240,867,527 |
| TOTAL | | $ 284,263,392 |

Securities carried at $78,455,274 in the above statement are deposited with various states as required by law.

Securities carried on the basis prescribed by the National Association of Insurance Commissioners. On the basis of market quotations for all bonds and stocks owned, the Company's total admitted assets at December 31, 2022 would be $266,908,407 and surplus as regards policyholders $223,512,542.

I, LAURA J. LAZARCZYK, Corporate Secretary of the FIDELITY AND DEPOSIT COMPANY OF MARYLAND, do hereby certify that the foregoing statement is a correct exhibit of the assets and liabilities of the said Company on the 31st day of December, 2022.

Laura J. Lazarczyk

*Corporate Secretary*

State of Illinois
City of Schaumburg } SS:

Subscribed and sworn to, before me, a Notary Public of the State of Illinois, in the City of Schaumburg, this 15th day of March, 2023.

RYAN HORGAN
Official Seal
Notary Public - State of Illinois
My Commission Expires Dec 10, 2024

*Notary Public*

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

### Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Cranbury Pharmaceuticals, LLC

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 2031 US Highway 130, Suite F

City: Monmouth Junction State: NJ Zip: 08852

Mailing Address (if different from physical address): c/o State License Servicing 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: cranburyPharma.com

Licensing Company Email: CPL@slsny.com

### Section 2: Personal Information

First: Janet Middle: E Last: Penner

Alias(es, nicknames, name changes, etc.): n/a

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: [redacted]ehigh Drive

City: Walnutport State: PA Zip: 18088

Telephone: [redacted] Email: jpenner@trispharma.com

Are you a citizen of the United States? ☐ Yes ■ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | X |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | X |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| York University | | | 1985 - 1987 | |
| Address | | City | State | Zip |
| 4700 Keele St | | Toronto, Ontario | Canada | M3J 1P3 |
| Diploma/Degree obtained, if any | | | | |
| MBA Degree | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| University of Western Ontario | | | 1982 - 1985 | |
| Address | | City | State | Zip |
| 1151 Richmond Street | | London, Ontario | Canada | N6A 3K7 |
| Diploma/Degree obtained, if any | | | | |
| BA Degree | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| Uxbridge Secondary School | | | 1978 - 1982 | |
| Address | | City | State | Zip |
| | | Uxbridge | Ontario | L0C 1K0 |
| Diploma/Degree obtained, if any | | | | |
| High School Diploma | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |
| School Name | | | From - To (MM/YY – MM/YY | |
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 08/2017 - Present | [redacted] Lehigh Drive | Walnutport | PA | 18088 |
| 06/1999 - 08/2017 | [redacted] Westfield Drive | Exton | PA | 19341 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Cranbury Pharmaceuticals, LLC | | | 05/2013 - Present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 2031 US Highway 130, Suite F | | Monmouth Junction | NJ | 08852 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| (732) 940-2800 | President | | ~ 20,800 hrs | |
| **Description of Duties** | | | | |
| Set up a new virtual Generic pharmaceutical company (Cranbury) to be the exclusive marketer of all Tris Pharma-developed generic products. • Launched new company into US Generic Pharmaceutical market only 2 months after start date. Within this time, set up a new 3PL relationship, completed new vendor registration with all major wholesalers and distributors, and negotiated contract prices and formulary placement with major customers. | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

Continue on next page if additional space is needed.

N/A

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✓ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✓ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✓ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✓ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # N/A. **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| Reason/Charge | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| Name of Business/Industry/Entity | | | | |

**Provide explanation below:**

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Janet E Penner, **certify that as the designated representative for**

Cranbury Pharmaceuticals, LLC,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. _____ I am at least 21 years of age;
3. _____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. _____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. _____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. _____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. _____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Janet E Penner
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

June 7 2023
Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Janet E Penner

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

June 7, 2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of NJ, ss. County of Middlesex

I, Janet Penner, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature** Janet E Penner

06/07/23

**Date**

Subscribed and Sworn to before me this 7th day of June 2023.

**Notary Public Signature**

KETAN SAPARIA
Commission # 50037377
Notary Public, State of New Jersey
My Commission Expires
May 03, 2026

**(Seal)**

| Cranbury Pharmaceuticals, LLC | |
|---|---|
| Employee List | |
| Janet Penner | President Generic Division |
| Jason Krakowski | Sales Operations Associate |
| Jheel Patel | Sales Operations |
| Kevin Walker | VP, Sales Generics |
| Maulik Parikh | Business Development, Manager |
| Shiphrah Kamble | National Account Manager |

## Barbara Blackburn

**From:** Compliance Department <compliance@slsnysupport.com>
**Sent:** Friday, July 7, 2023 8:19 AM
**To:** Barbara Blackburn
**Subject:** Re: [#181769] FW: Cranbury Pharmaceuticals, LLC- New Wholesaler application - Monmouth Junction, NJ

**WARNING** - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

**From:** State License Servicing, Inc.
**Subject:** New Wholesaler Initial Application - Monmouth Junction, NJ
**Client:** Cranbury Pharmaceuticals, LLC
**Ticket Number** #181769

Dear Nevada State Board of Pharmacy:
I hope this e-mail finds you well,

In regards to the DR information and their residency, I received confirmation from the DR that she is physically present at the site during regular business hours. She commutes from her home address in PA to the facility address in NJ.

Please let us know if you require anything further from us or if this will suffice to continue with the approval of this **Initial** permit.

Your response to this e-mail would be greatly appreciated.
Thank you in advance for your time and assistance.

Sincerely,

*Yanina Civile*
Customer Service
Pharmaregs, Inc.
State License Servicing, Inc
CIM 90, Carr. 165, Suite C-102
Guaynabo, PR 00968
Phone: (814) 350-7298

---

**From:** Barbara Blackburn <bblackburn@pharmacy.nv.gov>
**Date:** Monday, July 3, 2023 at 1:39 PM
**To:** CPL@slsny.com <CPL@slsny.com>, jpenner@trispharma.com <jpenner@trispharma.com>
**Cc:** Maria Herrera <m.herrera@pharmacy.nv.gov>
**Subject:** Cranbury Pharmaceuticals, LLC- New Wholesaler application - Monmouth Junction, NJ

The NVBOP received the NEW Wholesaler application today, 07.03.2023 for Cranbury Pharmaceuticals, LLC located in Monmouth Junction, NJ. Listed products handled includes controlled substances. To proceed with the application, a copy of the DEA certificate is required if handling-controlled substances.

In addition, we noticed that the designated representative's residence is in PA and not NJ so we need verification, as required by statute that the DR meets the following criteria:

1. Must be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
2. Must be employed full-time in a managerial level position with the pharmacy or wholesaler;
3. Must be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
4. May serve in this representative capacity for only one pharmacy or wholesaler at a time

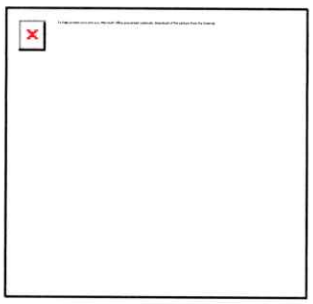
Please send the DEA registration certificate by email response and a statement confirming the DR qualifies based upon statutory criteria of all listed above.

Thank you in advance for assistance.

Barbara A. Blackburn
Licensing Specialist

**Nevada State**
**Board of Pharmacy**

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
Office: 775-850-1440 Ext. 131
Fax: 775-850-1444
Web Page: www.bop.nv.gov



# 4L

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

**Non-Refundable $1,000 Fee**

Rev (08/17/2022)

| **Where is the facility located?** | | ☐ Nevada ☑ Out-of-State |
|---|---|---|
| **Type of Application (check applicable box)** | | **Wholesaler Business Type (check applicable box)** |
| ☑ New Wholesaler<br>☐ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH N/A | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: Fidia Pharma USA Inc

Physical Address: 100 Campus Drive Suite 105

City: Florham Park State: NJ Zip: 07932

Mailing Address (if different from physical address): same as above

City: _____ State: _____ Zip: _____

Telephone: 973-507-5120 Website: www.fidiapharma.us

Name of Designated Representative (DR): Vivian Kelly

Licensing Company Email: vkelly@fidiapharma.us DR Email: vkelly@fidiapharma.us

| **Entities the Wholesaler will Serve (✓ all applicable)** | **Products to be Handled or Wholesaled (✓ all applicable)** | **Type of Wholesaling (✓ all applicable)** |
|---|---|---|
| ☐ Pharmacies | ☐ Dangerous Drugs | ☑ Manufacturer |
| ☑ Practitioners | ☐ Controlled Substances | ☐ Repacker |
| ☑ Hospitals | ☑ [a]Medical devices, equipment, supplies, gases See Attachment A | ☐ Reverse Distributor |
| ☑ Wholesalers | ☐ Others: | ☐ Warehouse |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ☑ Others: Clinics and Distributors | | ☐ Others: |

| **Section 2: History of Company** | **Yes** | **No** |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | x |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | x |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | x |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | x |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | x |

N/A

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

Date

[redacted]

Name: Besse Medical

Address: Accounts Payable PO Box 247 City: Thorofare State: NJ Zip: 08086

Name:

Address: City: State: Zip:

Name: McKesson Med Surgical

Address: PO Box 4059 City: Danville State: IL Zip: 61834

Name: Henry Schein

Address: PO Box 9 City: Bastian State: VA Zip: 24314

[redacted]

State of Incorporation:

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

[redacted]

State of Incorporation/Organization: Delaware

Parent Company (if any): Fidia Farmaceutic SpA

Corporation/Organization Name: Fidia Pharma USA Inc

Mailing Address: 100 Campus Drive Suite 105

City: Florham Park State: NJ Zip: 07932

Telephone: 973-507-5120 Email: vkelly@fidiapharma.us

Contact Person Name: Vivian Kelly

[redacted]

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

[redacted]

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | X |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | X | |
| 1. Copy of FDA registration See Attachment B<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment C | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** See Attachment D | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** N/A | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** See Attachment D | | ✓ | | |
| • **List of all partners and their percent ownership.** N/A | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment E | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment A | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** N/A | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) N/A | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment F | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment G | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ See Attachment A | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). See Attachment H | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. N/A | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. N/A | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Fidia Pharma USA Inc

Facility Name

Vivian Kelly

Print Name of Authorized Person Submitting Application

Vivian Kelly

Original signature of Authorized Person (copies or stamps not accepted)

7/17/2023

Date

| Board Use Only | Date Received: 7/26/23 | Amount: 1060-CK-3460 |
|---|---|---|

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[3] Medical Devices[4] Databases[5]

## Establishment Registration & Device Listing

New Search

Back To Search Results

**Establishment:**
FIDIA PHARMA USA INC.
100 Campus Drive, Suite 105
Florham Park, NJ 07932
**Registration Number:** 3009107511
**FEI Number*:** 3009107511
**Status:** Active
**Initial Distributor/Importer:** Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
**Date Of Registration Status:** 2023

**Owner/Operator:**
Fidia Pharma USA Inc.[6]
100 Campus Drive, Suite 105
Florham Park, NJ US 07932
**Owner/Operator Number:** 10037556[7]

**Official Correspondent:**
Vivian Kelly
100 Campus Drive, Suite 105
Florham Park, NJ 07932
**Phone:** 973-5776202

verified MJT 6/1/23

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

**Links on this page:**

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10037556&OwnerOperatc
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10037556&OwnerOperatc

Page Last Updated: 06/19/2023

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

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U.S. Department of Health & Human Services

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4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10037556&OwnerOperatc

**Attachment D**

**Corporate Officer and Director Information**

Fidia Pharma USA Inc

Carlo Pizzocaro, Chairman of the Board Antonio D
Marielli, President
Eric D. Kuhn, Secretary
Ranieri Venerosi Presciolini, Legal - Corporate Lawyer

# Delaware

The First State



I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "FIDIA PHARMA USA INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRTEENTH DAY OF JULY, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "FIDIA PHARMA USA INC." WAS INCORPORATED ON THE TWENTY-THIRD DAY OF MAY, A.D. 2011.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

4986150 8300

SR# 20232991516

Authentication: 203744528

Date: 07-13-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

**NEW JERSEY DEPARTMENT OF HEALTH**
**CONSUMER AND ENVIRONMENTAL HEALTH SERVICE**
**P.O. Box 369, Trenton, New Jersey 08625-0369**

0747734

## DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☐ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

100 CAMPUS DR, STE 105 FLORHAM PARK, NJ 07932-

Reg. No.
5004244

FIDIA PHARMA USA
100 CAMPUS DR, STE 105
FLORHAM PARK, NJ 07932-

**ISSUED PURSUANT TO**
**N.J.S.A. 24:6B**

**EXPIRES: January 31, 2024**

*Establishment Copy*

ACORD®

# CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
03/07/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

**PRODUCER**
Marsh USA, Inc.
9830 Colonnade Blvd, Suite 410
San Antonio, TX 78230
Attn: ROW.CertRequest@Marsh.com

CN996664091-Stnd-GW-22-24

**CONTACT NAME:**
**PHONE (A/C, No, Ext):** **FAX (A/C, No):**
**E-MAIL ADDRESS:**

| INSURER(S) AFFORDING COVERAGE | NAIC # |
|---|---|
| INSURER A : Steadfast Insurance Company | 26387 |
| INSURER B : Zurich | |
| INSURER C : | |
| INSURER D : | |
| INSURER E : | |
| INSURER F : | |

**INSURED**
Fidia Pharma USA Inc.
100 Campus Drive, Suite 105
Florham Park, NJ 07932

**COVERAGES** **CERTIFICATE NUMBER:** HOU-003995153-01 **REVISION NUMBER:** 1

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

| INSR LTR | TYPE OF INSURANCE | ADDL INSD | SUBR WVD | POLICY NUMBER | POLICY EFF (MM/DD/YYYY) | POLICY EXP (MM/DD/YYYY) | LIMITS | |
|---|---|---|---|---|---|---|---|---|
| A | X COMMERCIAL GENERAL LIABILITY | | | GLC824999512 | 01/01/2023 | 01/01/2024 | EACH OCCURRENCE | $ 5,000,000 |
| | X CLAIMS-MADE ☐ OCCUR | | | | | | DAMAGE TO RENTED PREMISES (Ea occurrence) | $ 100,000 |
| | | | | | | | MED EXP (Any one person) | $ 5,000 |
| | | | | | | | PERSONAL & ADV INJURY | $ 5,000,000 |
| | GEN'L AGGREGATE LIMIT APPLIES PER: | | | | | | GENERAL AGGREGATE | $ 5,000,000 |
| | X POLICY ☐ PRO-JECT ☐ LOC | | | | | | PRODUCTS - COMP/OP AGG | $ 5,000,000 |
| | OTHER: | | | | | | | $ |
| | AUTOMOBILE LIABILITY | | | | | | COMBINED SINGLE LIMIT (Ea accident) | $ |
| | ANY AUTO | | | | | | BODILY INJURY (Per person) | $ |
| | OWNED AUTOS ONLY ☐ SCHEDULED AUTOS | | | | | | BODILY INJURY (Per accident) | $ |
| | HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY | | | | | | PROPERTY DAMAGE (Per accident) | $ |
| | | | | | | | | $ |
| | UMBRELLA LIAB ☐ OCCUR | | | | | | EACH OCCURRENCE | $ |
| | EXCESS LIAB ☐ CLAIMS-MADE | | | | | | AGGREGATE | $ |
| | DED ☐ RETENTION $ | | | | | | | $ |
| B | WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N | | | WC931285012 | 12/31/2022 | 12/31/2023 | X PER STATUTE ☐ OTH-ER | |
| | ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N | N/A | | | | | E.L. EACH ACCIDENT | $ 1,000,000 |
| | (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below | | | | | | E.L. DISEASE - EA EMPLOYEE | $ 1,000,000 |
| | | | | | | | E.L. DISEASE - POLICY LIMIT | $ 1,000,000 |

**DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)**
Evidence of Insurance

**CERTIFICATE HOLDER**

Fidia Pharma USA Inc.
100 Campus Drive, Suite 105
Florham, NJ 07932

**CANCELLATION**

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

**AUTHORIZED REPRESENTATIVE**

Marsh USA Inc.

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The ACORD name and logo are registered marks of ACORD

**Attachment F**

**List of Employees, Consultants & Contractors**

| Office Employees, Consultants & Contractors | |
|---|---|
| Marielli, Antonio | President and CEO |
| Bajnath, Pamela | Human Resources Director |
| Bennett, Michael | Manager, Managed Markets & Reimbursement |
| Boe, Kevin | National Sales Director |
| Brown, Hubert | Accounting Specialist |
| Chen, Jane, PhD | Medical Science Liaison Consultant |
| DeCoite, Cristina | Procurement Manager |
| DeRobertis, Matthew | Customer Account Specialist |
| Dowling, David | Manager, Managed Markets and Reimbursement – East |
| Filter, Karen | Executive Specialty Sales |
| Jones, Ashley | Specialty Sales Representative |
| Hughes, Denise | Customer Service Manager |
| Kapadia, Chandani | Staff Accountant |
| Kelly, Vivian | Director, Regulatory Affairs |
| Larkin, Richard | Regulatory Consultant |
| Meyers, Sandra | Marketing Manager |
| Moeller, Edward | National Account Manager - Head of Training |
| Moran, Chris | Customer Service Lead |
| Nasir, Saad | Medical Director |
| Patel, Chirag | Senior Accountant |
| Patel, Pinal | Financial Controller |
| Propharma Group | Regulatory Consulting |
| Raina, Supriya | Head of Marketing |
| Rubino, Joseph | Director, Managed Markets and Reimbursement |
| Schulte, Christopher | Director of Commercial Operations |
| Sukoff, Morrie | Director of Advanced Wound Care Division |
| Taft, Fred | Commercial Director of Wound Care/Skin Care |
| Wong, Delores, RPh, PharmD | Medical Science Liaison Consultant |
| Wang, Xiaoying | Senior Regulatory Affairs Specialist |
| Waszak, Christina | Pharmacovigilance Quality Assurance Associate |
| Sales | |
| Montelibano, Jake | Executive District Sales Manager |
| Nevins, Matthew | Specialty Sales Representative |
| Bergknopf, Amy | Sr. Executive Specialty Sales |
| White, Mike | Specialty Sales Representative |
| Vojka, Dorand | Executive Specialty Sales |
| Augello, Lorenzo | Executive Specialty Sales |
| Stojkovic, Ned | Specialty Sales Professional |
| Licari, Anthony | Specialty Sales Representative |
| Fink, Nikki | Specialty Sales Representative |
| Martinez, Isaias | District Sales Manager |
| Johnson, Desmond | Specialty Sales Representative |
| Williams, Suzanne | Specialty Sales Professional |
| Tiltman, Helena | Specialty Sales Representative |
| Firor, Mikki | Specialty Sales Representative |
| Heath, Emmett | Sr. Executive Specialty Sales |
| Plumlee, Katlin | Specialty Sales Representative |
| Johnson, Travis | Specialty Sales Representative |
| Rosky, Andy | Sr. District Sales Manager |
| Martinez, Alberto | Specialty Sales Professional |
| Rivera, William | Specialty Sales Representative |
| Mellen, Barbara | Sr. Executive Specialty Sales |
| Jennings, John | Specialty Sales Associate |
| Ruffin, Larry | Specialty Sales Representative |
| Ransefore, Henri' | Specialty Sales Representative |

| | |
|---|---|
| Jenson, Casey | Specialty Sales Associate |
| McDonnel, J Patrick | Specialty Sales Representative |
| Robinson, Mike | District Sales Manager |
| Zavorksi, Courtney | Specialty Sales Representative |
| Wojcik, Ashley | Sr. Executive Specialty Sales |
| Bolyea, Natalie | Specialty Sales Representative |
| Marsters, Frank | Specialty Sales Representative |
| Semple, Jordan | Specialty Sales Representative |
| Jarman, Connor | Specialty Sales Associate |
| Tonery, Michael | District Sales Manager |
| Monachino, Samantha | Specialty Sales Representative |
| Winters, Sherilyn | Specialty Sales Representative |
| Gonzalez, Petrina | Specialty Sales Representative |
| Hinesley, TJ | Specialty Sales Representative |

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

**Section 1: Pharmacy/Wholesaler Information**

Name of Pharmacy/Wholesaler: Fidia Pharma USA Inc

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 100 Campus Drive Suite 105

City: Florham Park State: NJ Zip: 07932

Mailing Address (if different from physical address): same as above

City: State: Zip:

Telephone: 973-507-5120 Website: www.fidiapharma.us

Licensing Company Email: vkelly@fidiapharma.us

**Section 2: Personal Information**

First: Vivian Middle: Marie Last: Kelly

Alias(es, nicknames, name changes, etc.): N/A Vivian Marie Tomasello (nee) and Vivian T. DeVita

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex ☐ M ■ F ☐ X

Mailing Address: 100 Campus Drive Suite 105

City: Florham Park State: NJ Zip: 07932

Telephon[redacted] Email: vkelly@fidiapharma.us

Are you a citizen of the United States? ■ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Saddle Brook High School (Degree in name of Vivian M Tomasello) | | 09/1970 - 6/1974 | |
| **Address** | **City** | **State** | **Zip** |
| 355 Mayhill St. | Saddle Brook | NJ | 07663 |
| Diploma/Degree obtained, if any | | | |
| High School | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Rutgers University, NCAS (Degree in name of Vivian M Tomasello) | | 9/1974 - 5/1978 | |
| **Address** | **City** | **State** | **Zip** |
| 195 University Ave. | Newark | NJ | 07102 |
| Diploma/Degree obtained, if any | | | |
| BS, Medical Technology | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Seton Hall University | | 9/1979 - 5/1984 | |
| **Address** | **City** | **State** | **Zip** |
| 400 South Orange Ave. | South Orange | NJ | 07079 |
| Diploma/Degree obtained, if any | | | |
| MS in Biology with a minor in business (Degree in the name of Vivian T DeVita) | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 1993 - present | [redacted] 34th Street | Fair Lawn | NJ | 07410 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Fidia Pharma USA Inc | | | 3/24/2014 - present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 100 Campus Drive Suite 105 | | Florham Park | NJ | 07932 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 973-507-5120 | Director, Regulatory Affairs | | 1,500 + | |
| **Description of Duties** | | | | |
| Director of regulatory affairs, quality assurance and compliance to comply with the various federal, state, and local laws and regulations Responsibilities include regulatory submissions to FDA and CMS, oversight of the company's quality system and compliance for interactions with healthcare professionals. | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

Continue on next page if additional space is needed.

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

N/A

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| Reason/Charge | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| Name of Business/Industry/Entity | | | | |

**Provide explanation below:**

Vivian Kelly
Original Signature (electronic, copies or stamps not accepted)

7/17/2023
Date

I, Vivian Kelly, **certify that as the designated representative for**

Fidia Pharma USA Inc,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. VK I am at least 21 years of age;
3. VK I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. VK I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. VK I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. VK I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. VK I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Vivian Kelly

Print Name (First, Last)

Vivian Kelly

Original Signature (electronic, copies or stamps not accepted)

1/17/2023

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Vivian Kelly

Print Name (First, Last)

Vivian Kelly

Original Signature (electronic, copies or stamps not accepted)

7/5/2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of New Jersey, ss. County of Morris

I, Vivian Kelly, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Vivian Kelly

**Original Signature**

7/5/2023

**Date**

Subscribed and Sworn to before me this 5 day of July 2023.

Pinal Patel

**Notary Public Signature**

Pinal Patel
NOTARY PUBLIC
STATE OF NEW JERSEY
ID # 50000430
MY COMMISSION EXPIRES 07/16/2024

(Seal)

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

[redacted]

Name of MDEG Fidia Pharma USA Inc MDEG License # (if applicable) _____

Physical Address 100 Campus Drive Suite 105

City Florham Park State NJ Zip 07932

Mailing Address (if different from physical address) same as above

City _____ State _____ Zip _____

Telephone 973-507-5120 Website www.fidiapharma.us

Licensing Company Email vkelly@fidiapharma.us

[redacted]

First Vivian Middle Marie Last Kelly

Alias(es, nicknames, name changes, etc.) N/A Vivian Marie Tomasello (nee) and Vivian T. DeVita

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ■ F ☐ X

Mailing Address 100 Campus Drive Suite 105

City Florham Park State NJ Zip 09732

Telephone [redacted] Email vkelly@fidiapharma.us

Are you a citizen of the United States? ■ Yes ☐ No

| [redacted] | | |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| [redacted] | | |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A | | |

[redacted]

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Saddle Brook High School, 355 Mayhill St, , NJ 07663 (Degree in name of Vivian M Tomasello) | | 09/1970 - 6/1974 | |
| Address | City | State | Zip |
| 355 Mayhill St. | Saddle Brook | NJ | 07663 |
| Diploma/Degree obtained, if any | | | |
| High School | | | |
| School Name | | From - To (MM/YY – MM/YY) | |
| Rutgers University, NCAS (Degree in name of Vivian M Tomasello) | | 9/1974 - 5/1978 | |
| Address | City | State | Zip |
| 195 University Ave. | Newark | NJ | 07102 |
| Diploma/Degree obtained, if any | | | |
| BS, Medical Technology | | | |
| School Name | | From - To (MM/YY – MM/YY) | |
| Seton Hall University | | 9/1979 - 5/1984 | |
| Address | City | State | Zip |
| 400 South Orange Ave. | South Orange | NJ | 07079 |
| Diploma/Degree obtained, if any | | | |
| MS in Biology with a minor in business (Degree in the name of Vivian T DeVita) | | | |
| School Name | | From - To (MM/YY – MM/YY) | |
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |
| School Name | | From - To (MM/YY – MM/YY | |
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

[redacted]

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 1993 - present | [redacted]34th Street | Fair Lawn | NJ | 07410 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

[redacted]

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Fidia Pharma USA Inc | | 3/24/2014 - present | |
| **Business Address** | **City** | **State** | **Zip** |
| 100 Campus Drive Suite 105 | Florham Park | NJ | 07932 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| 973-507-5120 | Director, Regulatory Affairs | 1,500 + | |

**Description of Duties**
Director of regulatory affairs, quality assurance and compliance to comply with the various federal, state, and local laws and regulations Responsibilities include regulatory submissions to FDA and CMS, oversight of Fidia's quality system and compliance for interactions with healthcare professionals.

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |

**Description of Duties**

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |

**Description of Duties**

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |

**Description of Duties**

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |

**Description of Duties**

Continue on next page if additional space is needed.

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state? | | ✔ |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline. | | ✔ |

**Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:** N/A

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Vivian Hall
Original Signature (electronic, copies or stamps not accepted)

7/17/2023
Date

I, Vivian Kelly, **certify that as the MDEG Administrator for**

Fidia Pharma USA Inc,

**that I (initial that you have read and meet the following requirements):**

1. VK Have a high school diploma or its equivalent;
2. VK Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. VK Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. VK Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Vivian Kelly
Print Name (First, Last)

Vivian Kelly
Original Signature (electronic, copies or stamps not accepted)

7/12/2023
Date

| **Board Use Only** | Date Received: |
|---|---|

# NEVADA STATE BOARD OF PHARMACY

**431 W Plumb Lane**
**Reno, NV 89509**
**(775) 850-1440**
**Fax: (775) 850-1444**

## PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. PR2747476

Application/License No. _____

Fidia Pharma USA Inc ^^^^^^^ _____, doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
985 Damonte Ranch parkway Suite 206 Reno, NV 89521, as
Address of Applicant/Principal
PRINCIPAL, and Platte River Insurance Company, a
Surety Company
corporation organized under the laws of the state of Nebraska
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
P.O. Box 5900, Madison, WI 53705 - 0900 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 6/28/2023 ^^^^^.
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

PR2747476

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 18th day of July, 2023

APPLICANT/PRINCIPAL
Fidia Pharma USA Inc

Authorized Representative

SURETY COMPANY
Platte River Insurance Company

Surety Company's Representative

Ryan Tash Attorney-in-Fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

# PLATTE RIVER INSURANCE COMPANY
# POWER OF ATTORNEY

PR2747476
Bond Number

**KNOW ALL MEN BY THESE PRESENTS**, That the **PLATTE RIVER INSURANCE COMPANY**, a corporation of the State of Nebraska, having its principal offices in the City of Middleton, Wisconsin, does make, constitute and appoint

----------JOHN T. PAGE; RYAN TASH; SUSAN FOURNIER----------

its true and lawful Attorney(s)-in-fact, to make, execute, seal and deliver for and on its behalf, as surety, and as its act and deed, any and all bonds, undertakings and contracts of suretyship, provided that no bond or undertaking or contract of suretyship executed under this authority shall exceed in amount the sum of

----------WRITTEN INSTRUMENTS IN AN AMOUNT NOT TO EXCEED : $20,000,000.00----------

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of **PLATTE RIVER INSURANCE COMPANY** at a meeting duly called and held on the 8th day of January, 2002.

"**RESOLVED**, that the President, Executive Vice President, Vice President, Secretary or Treasurer, acting individually or otherwise, be and they hereby are granted the power and authorization to appoint by a Power of Attorney for the purposes only of executing and attesting bonds and undertakings, and other writings obligatory in the nature thereof, one or more resident vice-presidents, assistant secretaries and attorney(s)-in-fact, each appointee to have the powers and duties usual to such offices to the business of this company; the signature of such officers and seal of the Company may be affixed to any such power of attorney or to any certificate relating thereto by facsimile, and any such power of attorney or certificate bearing such facsimile signatures or facsimile seal shall be valid and binding upon the Company, and any such power so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking or other writing obligatory in the nature thereof to which it is attached. Any such appointment may be revoked, for cause, or without cause, by any of said officers, at any time."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and authority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner – Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

**IN WITNESS WHEREOF**, the **PLATTE RIVER INSURANCE COMPANY** has caused these presents to be signed by its officer undersigned and its corporate seal to be hereto affixed duly attested, this 1st day of January, 2020.

**Attest:**

Ryan J. Byrnes
Senior Vice President,
Chief Financial Officer and Treasurer

Suzanne M. Broadbent
Assistant Secretary

PLATTE RIVER INSURANCE COMPANY — CORPORATE SEAL — NEBRASKA

**PLATTE RIVER INSURANCE COMPANY**

John L. Sennott, Jr.
Chief Executive Officer and President

STATE OF WISCONSIN
COUNTY OF DANE } S.S.:

On the 1st day of January, 2020 before me personally came John L. Sennott, Jr., to me known, who being by me duly sworn, did depose and say: that he resides in the County of Hartford, State of Connecticut; that he is Chief Executive Officer and President of **PLATTE RIVER INSURANCE COMPANY**, the corporation described in and which executed the above instrument; that he knows the seal of the said corporation; that the seal affixed to said instrument is such corporate seal; that it was so affixed by order of the Board of Directors of said corporation and that he signed his name thereto by like order.

DAVID J. REGELE — NOTARY PUBLIC — STATE OF WISCONSIN

David J. Regele
Notary Public, Dane Co., WI
My Commission Is Permanent

STATE OF WISCONSIN
COUNTY OF DANE } S.S.:

I, the undersigned, duly elected to the office stated below, now the incumbent in **PLATTE RIVER INSURANCE COMPANY**, a Nebraska Corporation, authorized to make this certificate, **DO HEREBY CERTIFY** that the foregoing attached Power of Attorney remains in full force and has not been revoked; and furthermore, that the Resolution of the Board of Directors, set forth in the Power of Attorney is now in force.

Signed and sealed at the City of Middleton, State of Wisconsin this 18 day of July, 2023.

PLATTE RIVER INSURANCE COMPANY — CORPORATE SEAL — NEBRASKA

Andrew B. Diaz-Matos
Senior Vice President, General Counsel and Secretary

THIS DOCUMENT HAS BEEN GENERATED FOR A SPECIFIC BOND. IF YOU HAVE ANY QUESTIONS CONCERNING THE AUTHENTICITY OF THIS DOCUMENT CALL 800-475-4450.

# 4M

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

**Non-Refundable $1,000 Fee**

Rev (08/17/2022)

4

| Where is the facility located? | | ☐ Nevada ☒ Out-of-State |
|---|---|---|
| **Type of Application (check applicable box)** | | **Wholesaler Business Type (check applicable box)** |
| ☐ New Wholesaler<br>☒ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH 01636 | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☒ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: Medline Industries, LP

Physical Address: One Medline Place

City: Mundelein State: IL Zip: 60060

Mailing Address (if different from physical address): Three Lakes Drive - 3D

City: Northfield State: IL Zip: 60093

Telephone: 847-949-5500 Website: www.medline.com

Name of Designated Representative (DR): Adolfo Ortiz-Sepulveda

Licensing Company Email: ralicensing@medline.com DR Email: aortiz-sepulveda@medline.com

| Entities the Wholesaler will Serve (✓ all applicable) | Products to be Handled or Wholesaled (✓ all applicable) | Type of Wholesaling (✓ all applicable) |
|---|---|---|
| ☒ Pharmacies | ☒ Dangerous Drugs | ☐ Manufacturer |
| ☒ Practitioners | ☐ Controlled Substances | ☐ Repacker |
| ☒ Hospitals | ☒ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ☒ Wholesalers | ☒ Others: Cosmetics, Veterinary Legend Pharmaceuticals | ☒ Warehouse |
| ☒ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ☒ Others: Assisted Living, Surgical Centers Nursing Homes | | ☐ Others: |

| Section 2: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | X |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | X |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | X | |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | X |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | X |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # 3. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

See Attached Corporate Disciplinary sheet

Mary K Leonard

Original Signature (electronic, copies or stamps not accepted)

10/26/22

Date

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: Pfizer Inc.
Address: 235 E 42nd Street City: New York State: NY Zip: 10017

Name: ICU Medical
Address: 951 Calle Amanecer City: San Clemente State: CA Zip: 92673

Name: Baxter Healthcare
Address: 1 Baxter Parkway City: Deerfield State: IL Zip: 60015

Name: B Braun Medical Inc.
Address: 824 12th Ave City: Bethelem State: PA Zip: 18018

**Section 4: Publicly Traded Corporation**

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization:
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

**Section 6: Partnership**

Partnership Name: Medline Industries, LP
Mailing Address: Three Lakes Drive
City: Northfield State: IL Zip: 60093
Telephone: 847-949-5500 Email: ralicensing@medline.com
Contact Person Name: Tanya Hughes

**Section 7: Sole Owner**

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | ✔ |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | ✔ | |
| 1. Copy of FDA registration<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** | | ✓ | | |
| • **List of all partners and their percent ownership.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Medline Industries, LP

Facility Name

Mary K. Leonard

Print Name of Authorized Person Submitting Application

Mary K Leonard

Original signature of Authorized Person (copies or stamps not accepted)

Date

| Board Use Only | Date Received: 12-12-22 | Amount: 1000.00 CK-100053136 |
|---|---|---|

Medline Industries, LP- Discipline *Confidential*

| Date | Facility | Description of State Action | Corrective Actions |
|---|---|---|---|
| 8/3/2005 | 1401 N. Universal Ave<br>Kansas City, MO 64120 | **FILE CLOSED 2010**<br>Medline Industries' Kansas City, MO facility (#2003031660) was disciplined for failure to renew on time and for deficient temperature control procedures. Medline was placed on probation for 5 years. The state conducted multiple inspections of the facility throughout the probationary period and found Medline to comply with all requirements. The probationary period closed in August 2010. | Medline's Regulatory Affairs Department was significantly expanded to include a team of 7 Licensing Specialists that monitor and ensure our licenses are renewed on time. A temperature control room was constructed at the facility to ensure product is stored at the appropriate temperature and humidity. These control rooms are now a standard feature at our distribution centers. We worked closely with NABP to ensure that our temperature control facilities and procedures align with industry best practices throughout our distribution network. |
| 12/7/2006 | 9101 Riverside Pkwy<br>Lithia Springs, GA 30122 | **FILE CLOSED 2008**<br>The Florida Certified Designated Representative at the Georgia facility unexpectedly resigned. The state of Florida suspended Medline's Florida Out of State Rx Drug Wholesale Distributor Permit (#23:1470) until a new licensed Florida CDR was hired at the facility. | To prevent this for occurring in the future, all Florida licensed Medline facilities are required to have multiple Florida Certified Designated Representatives on staff. |
| 11/16/2007 | 10601 Southport Dr.<br>Orlando, FL 32824<br>401 Commerce Blvd.<br>Oldsmar, FL 34677<br>4750 118th Ave N<br>Clearwater, FL 33762 | **FILE CLOSED 2008**<br>Medline Industries was cited for several violations. Failure to pass and maintain a Florida compliant pedigree. Maintaining the wrong permit type for the activities performed in the facilities (in addition to a manufacturing permit, Florida required the facility a repackager permit). Distribution of saline to an unauthorized recipient. Additionally an Rx drug item was found at an unlicensed raw materials storage facility. Medline challenged several violations, resulting in most being substantially reduced or removed. Medline was assessed and paid a fine for these violations. All issues were addressed and resolved to the satisfaction of the FL DOH.<br><br>After duly notifying state authorities, as required by law, Medline received a fined from New York for out-of-state professional misconduct. (Cal. No. 27278) | To address the pedigree issues, Medline instituted a Florida specific pedigree system. This program ensured that any pedigree shipments within our distribution network with potential to end up in Florida has the required Florida documentation. (Note - these requirements have since been preempted by federal law). To address the issue of the wrong permit type, Medline secured the repackaging permit. To address the sale of saline to an unauthorized person, Medline instituted a new procedure for obtaining and maintaining customer licenses for all Rx Drug purchases- this procedure generates an automatic block for any Rx Drug order by an unlicensed customer. The Rx Drug item unintentionally stored in the raw materials facility was properly disposed of. Waste disposal procedures were updated to ensure that this mistake would not recur. |
| 11/26/2007 | 2708 NE Waldo Rd.<br>Gainesville, FL 32609 | **FILE CLOSED 2008**<br>Medline Industries' FL license (# 22:1022) was suspended for violations identified during a Florida BOP facility inspection. Medline, through Counsel, addressed the issues raised in the inspection and established that the suspension was unjustified. The suspension was lifted 3 days later on January 22, 2008. In 2010, Medline made an unrelated business decision to close this facility. (Case # 2007-37412) | After this inspection, Medline conducted a thorough review of its policies and procedures. Additionally, Medline implemented an internal auditing program to ensure that all distribution centers comply with internal policies and procedures and state and federal regulations. |
| 3/5/2008 | 149 New Camellia Blvd.<br>Covington, LA 70433 | **FILE CLOSED 2008**<br>Medline Industries (LA #4318) was cited for failure to properly maintain copies of current customer licenses on-site. Medline was assessed and paid a fine. (Louisiana Administrative Docket #2008006).<br><br>After duly notifying state authorities, as required by law, Medline received a fine from New York for out-of-state professional misconduct. (Cal. No. 27278) | In addition to storing copies of customers' licenses at headquarters, these licenses are now stored digitally so they can be accessed by our distribution centers. |
| 5/9/2008 | 5450 W. Stewart Ave.<br>Wausau, WI 54401 | **FILE CLOSED 2009**<br>Medline Industries (WI # 1116-045) was cited and fined by the Wisconsin Department of Regulation & Licensing following a facility inspection. Medline managed a portion of a Wisconsin hospital's warehouse. The inspector cited Medline for failure to install a dividing fence between the Medline warehouse and the hospital portion of the facility. All of the hospital products were owned by the hospital. Medline was also cited for failure to access policies and procedures during the inspection. Corrections were made and the facility re-inspected, to the satisfaction of the state (Case #08 | Immediately after the inspection, Medline and the owner of the facility erected a locked fence to divide the faculty. Medline also reviewed all of its other facilities to make sure no similar situations existed. In addition, training on where and how to access current policies and procedures was increased for distribution center personnel. This training is in addition to the training they receive on the policies and procedures themselves. |

## Medline Industries, LP- Discipline *Confidential*

| | | | |
|---|---|---|---|
| | | PHM 037). In 2010, Medline made an unrelated business decision to close this facility.<br><br>After duly notifying state authorities, as required by law, Medline received a fine from the states of Hawaii (Case #PHA 2009-7-L) and New York (Cal. No. 27278) for out-of-state professional misconduct. | |
| 8/21/2008 | 94-1420 Moaniani St. Waipahu, HI 96797 | **FILE CLOSED 2013**<br><br>Medline Industries, Inc. (PWD 115) was fined $5000 and placed on probation for 5 years for failure to report disciplinary actions within 30 days. Medline submitted all required notices, but missed the 30-day deadline. The probationary period ended in August 2013. (Case # PHA 2008-17-L) | Medline implemented a new process to notify the necessary licensing boards of future disciplinary actions within the required reporting timelines. |
| 3/19/2010 | 1401 N. Universal Ave.<br>Kansas City, MO 64120 | **FILE CLOSED 2010**<br><br>Medline Industries, Inc. applied for a Colorado Out-of-State Wholesaler license for the Kansas City, MO distribution center. The CO Board of Pharmacy issued a conditional license until the facility's MO probation period ended. (See 8/3/2005 discipline). Medline informed the CO Board when the MO probationary period was completed. Upon completion of probation, the Board issued a full license. | See 8/3/2005 discipline for corrective actions related to the underlying sanction. |
| 1/6/2021 | 1501 Harris Rd Libertyville, IL 60048 | **FILE CLOSED 2021**<br><br>Medline Industries, Inc. (OH License #01-1985050) received a fine of $250 from the Ohio Board of Pharmacy for the sale of dangerous drugs to an unlicensed entity. Medline maintained a current and valid DEA license on file for the physician rather than the TDDD license for the facility. The facility's TDDD license at the time of the sale had expired. The fine was paid on January 21, 2021 and the case was closed. (Case No. A-2020-0054 I-2019-0972-B.)<br><br>After duly notifying state authorities, as required by law, Medline received a $500 fine from the Alabama State Board of Pharmacy for the same underlying conduct as the Ohio matter. The fine was paid and the matter closed. (Case No:21-L-0048) | Medline takes this matter very seriously. Medline reviewed the customer licensing policies and procedures and updated internal requirements for the type of license required for customers in Ohio. Efforts were taken by Customer Licensing to research, ensure the proper type, and check license status for a large number of existing Ohio licenses. The Ohio TDDD licenses are reviewed on an annual basis to ensure compliance. |
| 11/1/2022 | 1040 Enterprise Parkway South West Jefferson, OH 43162 | **FILE CLOSURE PENDING**<br><br>Medline Industries, LP (OH License #01-30000190) entered a settlement agreement and agreed to pay a fine of $1,125.00 to the Ohio Board of Pharmacy for alleged sales of dangerous drugs to an unlicensed entity. Medline maintained a physician license on file versus a Terminal Distributor (TDDD) license. The TDDD license was added in May 2022- prior to this investigation. During the period of July 2021 to March 2022, the customer's TDDD license lapsed and Medline was unaware. Medline is in the process of notifying states of this fine. | Medline is committed to following all applicable state and federal statutes and regulations, including customer license requirements. Medline updated customer licensing requirements after the 01/06/2021 fine. This incident occurred while Medline was in the process of updating a large number of Ohio accounts. Medline is implementing additional steps to ensure compliance, including, increasing staffing, training, and resources for the customer licensing team. |

**Medline Industries, LP**
**FEIN 36-2596612**

**Limited Partnership Partners:**

| PARTNERS | Business Address | General or Limited | % of Ownership | FEIN |
|---|---|---|---|---|
| Mozart GP, LLC | Three Lakes Drive Northfield IL 60093 | General | 0% | 87-2508203 |
| Medline Borrower, LP | Three Lakes Drive Northfield IL 60093 | Limited | 100% | 87-2530238 |

**PARENT COMPANY INFORMATION:**
Medline Intermediate, LP
FEIN 87-2521736
State of Formation: IL
Managing Members:

**CORPORATE OFFICERS BUSINESS ADDRESS AND PHONE NUMBER FOR ALL LISTED HERE:**

**THREE LAKES DRIVE**
**NORTHFIELD IL 60093**
**PHONE #: 847-949-5500**

| Title | Name | Address |
|---|---|---|
| CEO | Charles N. Mills | 325 Shoreline Court, Glencoe, IL 60022 |
| COO | James D. Abrams | 405 Sheridan Road Highland Park, IL 60035 |
| CFO | Michael B. Drazin | 806 W. Kingsley Dr., Arlington Heights, IL 60004 |
| Chief Quality Officer | Lara N. Simmons | N5446 Cobblestone Rd Elkhorn, WI 53121 |

*File Number* S030704

# STATE OF ILLINOIS

## OFFICE OF THE SECRETARY OF STATE

## *To all to whom these Presents Shall Come, Greeting:*

*I, Jesse White, Secretary of State of the State of Illinois, do hereby certify that*

MEDLINE INDUSTRIES, LP, HAVING REGISTERED IN THE STATE OF ILLINOIS ON SEPTEMBER 07, 2021, APPEARS TO HAVE COMPLIED WITH ALL PROVISIONS OF THE UNIFORM LIMITED PARTNERSHIP ACT (2001) OF THIS STATE, AND AS OF THIS DATE IS IN GOOD STANDING AS A DOMESTIC LP/LLLP IN THE STATE OF ILLINOIS, HAVING FULFILLED ALL REQUIREMENTS OF SAID ACT WITH REGARD TO PAYMENT OF FEES, THE FILING OF ANNUAL REPORTS (IF APPLICABLE) AND NEITHER HAVING BEEN ADMINISTRATIVELY DISSOLVED BY THE SECRETARY OF STATE NOR HAVING VOLUNTARILY FILED A STATEMENT OF TERMINATION.

SEAL OF THE STATE OF ILLINOIS
AUG. 26TH 1818

Authentication #: 2225502154

Authenticate at: https://www.ilsos.gov

***In Testimony Whereof,*** *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 12TH *day of* SEPTEMBER *A.D.* 2022 .

Jesse White

SECRETARY OF STATE

# State of Illinois

## Department of Financial and Professional Regulation

### Division of Professional Regulation

LICENSE NO.
004.005192

The person, firm, or corporation whose name appears on this certificate has complied with the provisions of the Illinois Statutes and/or rules and regulations and is hereby authorized to engage in the activity as indicated below:

EXPIRES:
12/31/2024

LICENSED WHOLESALE DRUG DISTRIBUTOR

MEDLINE INDUSTRIES LP
ADOLFO ORTIZ-SEPULVEDA
1 MEDLINE PL
MUNDELEIN, IL 60060-4485

MARIO TRETO, JR.
SECRETARY

CECILIA ABUNDIS
DIRECTOR

The official status of this license can be verified at IDFPR.illinois.gov

17427016

Cut on Dotted Line

For future reference, IDFPR is now providing each person/business a unique identification number, 'Access ID', which may be used in lieu of a social security number, date of birth or FEIN number when contacting the IDFPR. Your Access ID is: 4523788

# Establishment Registration & Device Listing



New Search | Back To Search Results

**Establishment:**
MEDLINE INDUSTRIES - Mundelein
**Business Trade Name:**
MEDLINE INDUSTRIES - Dynacor

1204 Townline Rd
1 Medline Place
Mundelein, IL 60060
**Registration Number:** 3013429260
**FEI Number*:** 1000138386
**Status:** Active
**Date Of Registration Status:** 2023

**Owner/Operator:**
MEDLINE INDUSTRIES, LP
Three Lakes Drive
Northfield, IL US 60093
**Owner/Operator Number:** 1417592

**Official Correspondent:**
Matt C Clausen
Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093
**Phone:** 847-6434785

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Page Last Updated: 05/08/2023
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

# CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 06/26/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

| | |
|---|---|
| PRODUCER<br>MARSH USA LLC.<br>540 W. MADISON<br>CHICAGO, IL 60661<br><br>CN101705524-Stnd-GAWUP-23-24 USA | CONTACT NAME: Medline Industries, LP<br>PHONE (A/C, No, Ext): FAX (A/C, No):<br>E-MAIL ADDRESS: riskmanagement@medline.com |
| INSURED<br>Medline Industries Holdings, LP<br>Attn: Risk Management<br>Three Lakes Dr.<br>Northfield, IL 60093-2753 | INSURER(S) AFFORDING COVERAGE — NAIC #<br>INSURER A : Safety National Casualty Corporation — 15105<br>INSURER B : National Fire & Marine Insurance Co — 20079<br>INSURER C :<br>INSURER D :<br>INSURER E :<br>INSURER F : |

**COVERAGES** **CERTIFICATE NUMBER:** CHI-008941256-25 **REVISION NUMBER:** 7

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

| INSR LTR | TYPE OF INSURANCE | ADDL INSD | SUBR WVD | POLICY NUMBER | POLICY EFF (MM/DD/YYYY) | POLICY EXP (MM/DD/YYYY) | LIMITS | |
|---|---|---|---|---|---|---|---|---|
| A | X COMMERCIAL GENERAL LIABILITY<br>CLAIMS-MADE [X] OCCUR<br>GEN'L AGGREGATE LIMIT APPLIES PER:<br>X POLICY [ ] PRO-JECT [ ] LOC<br>OTHER: | | | GL 4065036 | 07/01/2023 | 07/01/2024 | EACH OCCURRENCE<br>DAMAGE TO RENTED PREMISES (Ea occurrence)<br>MED EXP (Any one person)<br>PERSONAL & ADV INJURY<br>GENERAL AGGREGATE<br>PRODUCTS - COMP/OP AGG | $ 1,000,000<br>$ 1,000,000<br>$ 10,000<br>$ 1,000,000<br>$ 2,000,000<br>$ SEE BELOW |
| A | AUTOMOBILE LIABILITY<br>X ANY AUTO<br>OWNED AUTOS ONLY<br>HIRED AUTOS ONLY<br>SCHEDULED AUTOS<br>NON-OWNED AUTOS ONLY | | | CA 6675933 | 07/01/2023 | 07/01/2024 | COMBINED SINGLE LIMIT (Ea accident)<br>BODILY INJURY (Per person)<br>BODILY INJURY (Per accident)<br>PROPERTY DAMAGE (Per accident) | $ 2,000,000<br>$<br>$<br>$ |
| B | X UMBRELLA LIAB X OCCUR<br>EXCESS LIAB CLAIMS-MADE<br>DED X RETENTION $ 10,000 | | | 42-UMO-100007-11 | 07/01/2023 | 07/01/2024 | EACH OCCURRENCE<br>AGGREGATE | $ 1,000,000<br>$ 1,000,000 |
| A<br>A | WORKERS COMPENSATION AND EMPLOYERS' LIABILITY<br>ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [Y] (Mandatory in NH)<br>If yes, describe under DESCRIPTION OF OPERATIONS below | N/A | | LDS 4065032 (AOS)<br>PS 4065034 (WI) | 07/01/2023<br>07/01/2023 | 07/01/2024<br>07/01/2024 | X PER STATUTE [ ] OTH-ER<br>E.L. EACH ACCIDENT<br>E.L. DISEASE - EA EMPLOYEE<br>E.L. DISEASE - POLICY LIMIT | $ 1,000,000<br>$ 1,000,000<br>$ 1,000,000 |
| B | Products/Completed Operations Liability | | | 42-PCO-301515-08 | 07/01/2023 | 07/01/2024 | Each Occurrence<br>Aggregate | 1,000,000<br>2,000,000 |

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Evidence of Insurance. Policies listed above includes coverage for all Medline Industries Holdings, LP., branch (listed on addendum).

**CERTIFICATE HOLDER**

Medline Industries Holdings, LP
Attn: Risk Management
Three Lakes Drive
Northfield, IL 60093-2753

**CANCELLATION**

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Marsh USA Inc.

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AGENCY CUSTOMER ID: CN101705524
LOC #: Chicago

ACORD

# ADDITIONAL REMARKS SCHEDULE



| AGENCY | NAMED INSURED |
|---|---|
| MARSH USA LLC. | MedLine Industries Holdings, LP<br>Attn: Risk Management<br>Three Lakes Dr.<br>Northfield, IL 60093-2753 |
| POLICY NUMBER | |
| CARRIER / NAIC CODE | EFFECTIVE DATE: |

**ADDITIONAL REMARKS**

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

B06 - One Medline Dr, Wilmer, TX 75172
B52 - 974 Main Street, Alamo, TN 38001
Laredo - SPT - 12013 General Milton Drive, Laredo, TX 78045
B51 - 60 Athlete's Way, Suite 100, Mount Juliet, TN 37122
C32 – 29895 US Hwy 90 Bus, Katy, TX 77494


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| First Name | Last Name | Job Title | Location |
|---|---|---|---|
| ERIC | WORRELL | Mgr Warehouse | MUND3 |
| ANITA | COCHRAN | OPS-Branch Administrator | MUND3 |
| MIGUEL | GAMINO-BRIZUELA | OPS-Branch Trainer | MUND3 |
| ALEX | GAVLICK | OPS-Branch Trainer | MUND3 |
| JUAN | PEDROZA | OPS-Branch Trainer | MUND3 |
| SYDNEY | ZINSKY | OPS-Branch Trainer | MUND3 |
| LORA | DIXON | OPS-Inventory Coord | MUND3 |
| JAMES | GEISSBERGER | OPS-Inventory Coord | MUND3 |
| TIMOTHY | BODECKER | OPS-Maintenance Mechanic I | MUND3 |
| DAVID | HOEKENGA | OPS-Maintenance Mechanic I | MUND3 |
| DEBORAH | MONAGHAN | OPS-Warehouse Clerk | MUND3 |
| ANA | PEDROZA | OPS-Warehouse Clerk | MUND3 |
| STEVEN | ANDRADE | OPS-Warehouse Ld | MUND3 |
| ABELARDO | JOVES | OPS-Warehouse Ld | MUND3 |
| FRANCISCO | MARTIN DEL CAMPO | OPS-Warehouse Ld | MUND3 |
| NICHOLAS | ALVAREZ | OPS-Warehouse Operator | MUND3 |
| JOSE | AMADOR | OPS-Warehouse Operator | MUND3 |
| LUIS | ARZATE | OPS-Warehouse Operator | MUND3 |
| KARL | AUS-DER-AU | OPS-Warehouse Operator | MUND3 |
| ERIC | AYALA | OPS-Warehouse Operator | MUND3 |
| AUSTIN | BELLER | OPS-Warehouse Operator | MUND3 |
| ALEXANDER | BLESSING | OPS-Warehouse Operator | MUND3 |
| DONOVAN | BROWN | OPS-Warehouse Operator | MUND3 |
| DOMINGO | CARLOS | OPS-Warehouse Operator | MUND3 |
| EDWIN | CASTANEDA | OPS-Warehouse Operator | MUND3 |
| RUBEN | CASTANEDA | OPS-Warehouse Operator | MUND3 |
| ANTHONY PAUL | CASTRO | OPS-Warehouse Operator | MUND3 |
| MANUEL | CAVAZOS | OPS-Warehouse Operator | MUND3 |
| LAWRENCE | COLVIN | OPS-Warehouse Operator | MUND3 |
| ANGELICA | CORREA | OPS-Warehouse Operator | MUND3 |
| ESTEBAN | CRUZ | OPS-Warehouse Operator | MUND3 |
| EDWIN | DE LA TORRE | OPS-Warehouse Operator | MUND3 |
| VINCENT | DIGGINS | OPS-Warehouse Operator | MUND3 |
| ALAN | DIXON | OPS-Warehouse Operator | MUND3 |
| DARIO | DORANTES | OPS-Warehouse Operator | MUND3 |
| JUSTIN | ENGLISH | OPS-Warehouse Operator | MUND3 |
| DAVID | ESTRADA | OPS-Warehouse Operator | MUND3 |
| JESUS | FLORES | OPS-Warehouse Operator | MUND3 |
| ERIKA | GADSDEN | OPS-Warehouse Operator | MUND3 |
| RAYMON | GARIEPY | OPS-Warehouse Operator | MUND3 |
| BRIAN | GOMEZ | OPS-Warehouse Operator | MUND3 |
| DANIEL | GRACEY | OPS-Warehouse Operator | MUND3 |
| PERLO | GREGORIO | OPS-Warehouse Operator | MUND3 |
| JESUS | GUILLEN | OPS-Warehouse Operator | MUND3 |
| HECTOR | GUTIERREZ MAYA | OPS-Warehouse Operator | MUND3 |
| CHARLES | HACKER | OPS-Warehouse Operator | MUND3 |

| | | | |
|---|---|---|---|
| HAYDEN | HANSELMANN | OPS-Warehouse Operator | MUND3 |
| JASON | HARDT JR | OPS-Warehouse Operator | MUND3 |
| AARON | HOUSER | OPS-Warehouse Operator | MUND3 |
| MAURICE | HUNT | OPS-Warehouse Operator | MUND3 |
| KURT | KRUSE | OPS-Warehouse Operator | MUND3 |
| RODRIGO | LILOC | OPS-Warehouse Operator | MUND3 |
| JOSEPH | LULAY | OPS-Warehouse Operator | MUND3 |
| MIKALA | MAGUIRE | OPS-Warehouse Operator | MUND3 |
| FIDEL | MARCOS LANDA | OPS-Warehouse Operator | MUND3 |
| ANDRES | MARTINEZ | OPS-Warehouse Operator | MUND3 |
| MITU | MATHEW | OPS-Warehouse Operator | MUND3 |
| JOSEPH | MCDONOUGH | OPS-Warehouse Operator | MUND3 |
| CHRISTIAN | MCGEE | OPS-Warehouse Operator | MUND3 |
| CESAR | MORALES-VILLALBA | OPS-Warehouse Operator | MUND3 |
| ANDREW | MUELLER | OPS-Warehouse Operator | MUND3 |
| ISMAEL | MURGUIA | OPS-Warehouse Operator | MUND3 |
| JAMES | MURPHY | OPS-Warehouse Operator | MUND3 |
| SAMUEL | NOLASCO | OPS-Warehouse Operator | MUND3 |
| ANGEL | OCHOA | OPS-Warehouse Operator | MUND3 |
| ORLANDO | ORTIZ | OPS-Warehouse Operator | MUND3 |
| MATTHEW | PADOLINA | OPS-Warehouse Operator | MUND3 |
| SAULO JORGE | RIVERA | OPS-Warehouse Operator | MUND3 |
| NICK | SARLO | OPS-Warehouse Operator | MUND3 |
| JAMES | SERSEN | OPS-Warehouse Operator | MUND3 |
| SOVANN | TES | OPS-Warehouse Operator | MUND3 |
| JAVIER | TRUJILLO | OPS-Warehouse Operator | MUND3 |
| JOSE | TRUJILLO | OPS-Warehouse Operator | MUND3 |
| TIMOTHY | TURNER | OPS-Warehouse Operator | MUND3 |
| GILBERTO | VAZQUEZ | OPS-Warehouse Operator | MUND3 |
| ADRIAN | VELAZQUEZ | OPS-Warehouse Operator | MUND3 |
| BORIS | VINOKUROV | OPS-Warehouse Operator | MUND3 |
| JALEN | YOUNG | OPS-Warehouse Operator | MUND3 |
| ADOLFO | ORTIZ-SEPULVEDA | Sr Mgr Operations | MUND3 |
| PATRICK | MARONEY | Sr Supv Warehouse | MUND3 |
| JAIME | BARROZO | Supv Warehouse | MUND3 |
| GEORGE | BRITT | Supv Warehouse | MUND3 |
| JOHN | PALACIO | Supv Warehouse | MUND3 |

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

### Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Medline Industries, LP

Pharmacy/Wholesaler License # (if applicable): WH01636

Physical Address: One Medline Place

City: Mundelein State: IL Zip: 60060

Mailing Address (if different from physical address): Three Lakes Drive - 3D

City: Northfield State: IL Zip: 60031

Telephone: 847-445-3153 Website: www.medline.com

Licensing Company Email: ralicensing@medline.com

### Section 2: Personal Information

First: Adolfo Middle: Last: Ortiz-Sepulveda

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] N Charlotte Dr

City: Wadsworth State: IL Zip: 60083

Telephone: [redacted] Email: aortiz-sepulveda@medline.com

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | X |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| State of California Stockton School For Adults | | 5/2012-7/2012 | |
| **Address** | **City** | **State** | **Zip** |
| 1525 Pacific Avenue | Stockton | CA | 95204 |
| Diploma/Degree obtained, if any | | | |
| GED | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Tokay High School | | 8/2001 - 5/2004 | |
| **Address** | **City** | **State** | **Zip** |
| 1111 W Century Blvd | Lodi | CA | 95240 |
| Diploma/Degree obtained, if any | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 5/1/22 - Current | [redacted] N Charlotte Drive | Wadsworth 26 Mi. DMV | IL | 60083 |
| 7/2019 - 4/30/22 | [redacted] N Louie Ln | Linden | CA | 95236 |
| 5/2014 - 7/2018 | [redacted] Lone St | Linden | CA | 95236 |
| 1/2011 - 5/2014 | [redacted] E Flora St | Stockton | CA | 95205 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | From - To (MM/YY – MM/YY) |
|---|---|---|
| Medline Industries, LP (formerly Medline Industries, Inc.) | | 4/2020 - Current |
| **Business Address** | **City** | **State / Zip** |
| One Medline Place | Mundelein | IL 60060 |
| **Phone** | **Title** | **Number of Employed Hours** |
| 847-643-3144 | Senior Operations Manager | 40 + hours weekly |

**Description of Duties**

Manages receiving, distribution and dispensing of prescription drugs and medical devices.
Monitors inventory, developed and trained Supervisors
See Attached Resume

| Business Name | | From - To (MM/YY – MM/YY) |
|---|---|---|
| Medline Industries, LP | | 4/2019-4/1/2020 |
| **Business Address** | **City** | **State / Zip** |
| One Medline Place | Mundelein | IL 60060 |
| **Phone** | **Title** | **Number of Employed Hours** |
| 847-643-3144 | Warehouse Manager | 40+ hours weekly |

**Description of Duties**

Assisted in developing to ensure pickers were picking items correctly. Developed and mainained picker shifts and schedules.

See Attached Resume

| Business Name | | From - To (MM/YY – MM/YY) |
|---|---|---|
| See Attached Resume | | |
| **Business Address** | **City** | **State / Zip** |
| | | |
| **Phone** | **Title** | **Number of Employed Hours** |
| | | |

**Description of Duties**

| Business Name | | From - To (MM/YY – MM/YY) |
|---|---|---|
| | | |
| **Business Address** | **City** | **State / Zip** |
| | | |
| **Phone** | **Title** | **Number of Employed Hours** |
| | | |

**Description of Duties**

| Business Name | | From - To (MM/YY – MM/YY) |
|---|---|---|
| | | |
| **Business Address** | **City** | **State / Zip** |
| | | |
| **Phone** | **Title** | **Number of Employed Hours** |
| | | |

**Description of Duties**

Continue on next page if additional space is needed.

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| N/A | | | |
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | X |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | X |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | X | |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | X | |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | X | |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | X |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | X |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | X |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | X |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question #** 4,5,6 **. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| Reason/Charge | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| Name of Business/Industry/Entity | | | | |

**Provide explanation below:**

See attached Corporate Disciplinar Report History

Original Signature (electronic, copies or stamps not accepted)

11/23/2022
Date

I, Adolfo Ortiz-Sepulveda, **certify that as the designated representative for**

Medline Industries, LP,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. AOS I am at least 21 years of age;
3. AOS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AOS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AOS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AOS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AOS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Adolfo Ortiz-Sepulveda

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/23/2022

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Adolfo Ortiz-Sepulveda

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/23/2022

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Illinois, ss. County of Lake

I, Adolfo Ortiz-Sepulveda, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

11/23/2022

**Date**

Subscribed and Sworn to before me this 23 day of November 2022.

OFFICIAL SEAL
MARK CALLOW
NOTARY PUBLIC, STATE OF ILLINOIS
LAKE COUNTY
MY COMMISSION EXPIRES 11/13/2024

**Notary Public Signature**

**(Seal)**

# ADOLFO ORTIZ

[redacted] N Charlotte Drive | Wadsworth, IL 60083 [redacted]

## PROFESSIONAL PROFILE

Successful Sr. Operations Manager and Leader who effectively formulates strategies, tactics, and action plans to cut cost, increase productivity and fosters continuous growth. Genuine pleasure from transforming high potential team members into outstanding leaders demonstrating the creativity to financial and operational success.

## CORE COMPETENCIES

- ✓ Certified trainer on Walkie, stand up, and reach forklifts along with cherry picker certification.
- ✓ Extensive knowledge of all supply chain and or warehouse operations such as Receiving, Shipping, Replenishment, Picking and Inventory Control.
- ✓ CPR/First Aid certified.
- ✓ Process Improvements
- ✓ Efficient in Excel, Word, Outlook and Power Point , SAP, Catalyst, Protrack
- ✓ Strategic Planning
- ✓ Systems Implementation
- ✓ Reporting
- ✓ Project Management
- ✓ Communication
- ✓ Team Building
- ✓ Procedure development

## EMPLOYMENT HISTORY

**Medline Industries Inc., Sr. Operations Manager**
**04/15/2020-Present**
*Mundelein, IL*

Responsible for overseeing warehousing operations to ensure development of teammates and implementation of continuous process improvements. Oversee acquisition and delivery of quality production materials. Researched, identified, and analyzed gaps in performance to create targeted action plans. Developed and launched new systems, processes, and procedures to comply with logistics best practices and corporate mission.

- Major KPI's included rec-ship accuracy and inventory accuracy.
- Led cross-functional team in the implementation of a new SAP WM system which transitioned the site
- From a paper-based logistics center to RF based.
- Directed the reconciliation of inventory in the operation.
- Managed cost and performance of maintenance/facilities provider for site.
- Implemented Operational Excellence Initiatives 5s , Kaizen
- Exceeded corporate safety goals for lost time incidents and DART rates .
- Procured all supplies for both sites; identified, negotiated and maintained vendor relationships

**Medline Industries Inc., Warehouse Manager** 4/1/2019 — 4/15/2020

- Responsible for operation of up to 40-50 employees in 600K SQ ft. facility
- Developed and trained new salaried managers and Supervisors
- Mentored coached and developed team members
- Enforced security policies and procedures to protect company assets from theft, loss or damage.

**Medline Industries, Inc., Sr. Supervisor** 5/1/2017 — 3/31/2019
*Manteca, CA*

- Responsible for operation of up to 40-50 employees in 600K SQ ft. facility
- Developed and trained new salaried managers and Supervisors
- Mentored coached and developed team members
- Enforced security policies and procedures to protect company assets from theft, loss or damage.
- Assessed upcoming projects to forecast projected resource requirements.
- Trained, mentored and motivated employees to maximize team
- Productivity.
- Conducted associate focus groups to gather personnel feedback,
- Address concerns and establish rapport across team members and leadership.
- Managed supply chain and monitored all logistics functions for company.
- Protected company brand and improved customer satisfaction by finding
- Creative solutions to problems arising from operational challenges.

**Medline Industries, Inc., Warehouse Supervisor** 05/01/2012 — 04/31/2017
*Stockton, CA*

- Responsible for operation of up to 40-50 employees
- Enforced security policies and procedures to protect company assets from theft, loss or damage.
- Assessed upcoming projects to forecast projected resource requirements.
- Trained, mentored and motivated employees to maximize team
- Productivity.
- Conducted associate focus groups to gather personnel feedback,
- Address concerns and establish rapport across team members and leadership.
- Managed supply chain and monitored all logistics functions for company.
- Protected company brand and improved customer satisfaction by finding
- Creative solutions to problems arising from operational challenges.

**Medline Industries, Inc., Warehouse Lead** **12/01/2010- 05/01/2012**
*Stockton, CA*

- Responsible for setting up workload for the shift
- Conduct training and development of new team members
- Audit standard processes
- Maintained a safe culture through accountability and safety programs
- Helped implement new RF system

**Medline Industries, Inc., Warehouse Operator** **11/03/2008- 11/31/2010**
***Stockton, CA***

- Unload floor loaded import containers
- Perform shipping and receiving activities
- Responsible for accurate load receipts.
- Used SAP RF System to receive product

## Education

GED High School Equivalency Diploma
*Department of Education*
*State of California*

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

### Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Medline Industries, LP MDEG License # (if applicable) N/A

Physical Address One Medline Place

City Mundelein State IL Zip 60060

Mailing Address (if different from physical address) Three Lakes Drive - 3D

City Northfield State IL Zip 60093

Telephone 847-643-4922 Website www.medline.com

Licensing Company Email ralicensing@medline.com

### Section 2: Personal Information

First Adolfo Middle Last Ortiz-Sepulveda

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] N Charlotte Drive

City Wadsworth State IL Zip 60083

Telephone [redacted] Email aortiz-sepulveda@medline.com

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.320) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 425.540) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | X |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Department of Education State of California | | | |
| **Address** | **City** | **State** | **Zip** |
| 1525 Pacific Ave | Stockton | CA | 95204 |
| **Diploma/Degree obtained, if any** | | | |
| GED | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 5/01/2022 - Current | [redacted]N Charlotte Dr. | Wadsworth | IL | 60083 |
| 7/2019 - 5/2022 | [redacted]Spruce Pointe Dr. | Gurnee | IL | 60031 |
| 7/2018 - 7/2019 | [redacted]N Louie Ln. | Linden | CA | 95236 |
| 5/2014 - 7/2019 | [redacted] lone St. | Linden | CA | 95236 |
| 1/2011 - 5/2014 | [redacted]E Flora St. | Stockton | CA | 95205 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Medline Industries, LP | | | 4/2020 - Current |
| **Business Address** | **City** | **State** | **Zip** |
| 1200 Townline Rd | Mundelein | IL | 60060 |
| **Phone** | **Title** | | **Number of Employed Hours** |
| 847-643-4922 | Director of Operations | | 40 + hours weekly |

Description of Duties

Responsible for overseeing warehousing operations to ensure development teammates and implementation of continuous process improvements Verifies incoming and outgoing shipments, handling and disposition of materials and keeping warehouse inventory current and accurate.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Medline Industries, Inc. | | | 4/2019 - 4/2020 |
| **Business Address** | **City** | **State** | **Zip** |
| 1200 Townline Rd | Mundelein | IL | 60060 |
| **Phone** | **Title** | | **Number of Employed Hours** |
| 847-643-4922 | Warehouse Manager | | 40 + hours weekly |

Description of Duties

Personally involved in the handling, distribution, shipping and record keeping of prescription drugs and devices. Oversees Sales and operations daily.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Medline Industries, Inc. | | | 11/2018 - 4/2019 |
| **Business Address** | **City** | **State** | **Zip** |
| 2325 W Louise Ave | Manteca | CA | 95337 |
| **Phone** | **Title** | | **Number of Employed Hours** |
| 847-643-4922 | Sr Warehouse Supervisor | | 40 + hours weekly |

Description of Duties

Personally involved in the handling, distribution, shipping and record keeping of prescription drugs and devices. Oversees Sales and operations daily.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | **Number of Employed Hours** |
| | | | |

Description of Duties

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | **Number of Employed Hours** |
| | | | |

Description of Duties

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| N/A | | | |
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | X |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state? | | X |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline. | | X |

**Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # _____. **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

6/8/2023
Date

I, Adolfo Ortiz-Sepulveda, **certify that as the MDEG Administrator for**

Medline Industries, LP,

**that I (initial that you have read and meet the following requirements):**

1. _____ Have a high school diploma or its equivalent;
2. _____ Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. _____ Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. _____ Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Adolfo Ortiz-Sepulveda
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/8/2023
Date

| **Board Use Only** | Date Received: 6/22/23 |
|---|---|

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/13/2022)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of Pharmacy/MDEG/Wholesaler Medline Industries, LP

Pharmacy/MDEG/Wholesaler License # (if applicable) WH01636

Physical Address One Medline Place

City Mundelein State IL Zip 60060

Mailing Address (if different from physical address) Three Lakes Drive

City Northfield State IL Zip 60093

Telephone 847-949-5500 Website www.medline.com

Licensing Company Email ralicensing@medline.com

**Section 2: Personal Information**

First Lara Middle N Last Simmons

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address Three Lakes Drive

City Northfield State IL Zip 60093

Telephone 847-949-5500 Email ralicensing@medline.com

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| University of Wisconsin - Parkside | | | 1986-1991 | |
| **Address** | | **City** | **State** | **Zip** |
| 900 Wood Rd | | Kenosha | WI | 53144 |
| **Diploma/Degree obtained, if any** | | | | |
| BA in Economics | | | | |

| School Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Waterford Union High School | | | 1982-1986 | |
| **Address** | | **City** | **State** | **Zip** |
| 611 W Main St | | Waterford | WI | 53185 |
| **Diploma/Degree obtained, if any** | | | | |
| Diploma | | | | |

| School Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| N/A | | | | |
| **Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Diploma/Degree obtained, if any** | | | | |
| | | | | |

| School Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| N/A | | | | |
| **Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Diploma/Degree obtained, if any** | | | | |
| | | | | |

| School Name | | | From - To (MM/YY – MM/YY | |
|---|---|---|---|---|
| N/A | | | | |
| **Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Diploma/Degree obtained, if any** | | | | |
| | | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 1997 - Present | [redacted]60th Street | Bristol | WI | 53104 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | From - To (MM/YY – MM/YY) |
|---|---|
| Medline Industries, LP formerly known as Medline Industries, Inc. | 1991 - Present |

| Business Address | City | State | Zip |
|---|---|---|---|
| Three Lakes Drive | Northfield | IL | 60093 |

| Phone | Title |
|---|---|
| 847-949-5500 | President QA/RA |

Description of Duties

See Attached

| Business Name | From - To (MM/YY – MM/YY) |
|---|---|
| N/A | |

| Business Address | City | State | Zip |
|---|---|---|---|
| | | | |

| Phone | Title |
|---|---|
| | |

Description of Duties

| Business Name | From - To (MM/YY – MM/YY) |
|---|---|
| | |

| Business Address | City | State | Zip |
|---|---|---|---|
| | | | |

| Phone | Title |
|---|---|
| | |

Description of Duties

| Business Name | From - To (MM/YY – MM/YY) |
|---|---|
| N/A | |

| Business Address | City | State | Zip |
|---|---|---|---|
| | | | |

| Phone | Title |
|---|---|
| | |

Description of Duties

| Business Name | From - To (MM/YY – MM/YY) |
|---|---|
| N/A | |

| Business Address | City | State | Zip |
|---|---|---|---|
| | | | |

| Phone | Title |
|---|---|
| | |

Description of Duties

Continue on next page if additional space is needed.

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| N/A | | | |
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| N/A | | | |
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| N/A | | | |
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| N/A | | | |
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| N/A | | | |
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✓ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | ✓ | |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | ✓ | |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | ✓ | |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question #** 4,5,6 **. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

See Attachment

Original Signature (electronic, copies or stamps not accepted)

9/19/21
Date

Applicant's initials LS

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Lara N. Simmons

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/15/22

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Illinois, ss. County of Lake

I, Lara N. Simmons, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

9/19/22

**Date**

Subscribed and Sworn to before me this 19 day of September 2022

**Notary Public Signature**

OFFICIAL SEAL
MARK CALLOW
NOTARY PUBLIC, STATE OF ILLINOIS
LAKE COUNTY
MY COMMISSION EXPIRES 11/13/2024

(Seal)

Applicant's initials LS

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/13/2022)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of Pharmacy/MDEG/Wholesaler Medline Industries, LP

Pharmacy/MDEG/Wholesaler License # (if applicable) WH01636

Physical Address One Medline Place

City Mundelein State IL Zip 60060

Mailing Address (if different from physical address) Three Lakes Drive

City Northfield State IL Zip 60093

Telephone 847-949-5500 Website www.Medline.com

Licensing Company Email ralicensing@medline.com

**Section 2: Personal Information**

First Charles Middle N Last Miller

Alias(es, nicknames, name changes, etc.) Charlie

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address Three Lakes Drive

City Northfield State IL Zip 60093

Telephone 847-949-5500 Email ralicensing@medline.com

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Cornell University | | 1979-1984 | |
| **Address** | **City** | **State** | **Zip** |
| 616 Thurston Avenue | Ithaca | NY | 14853 |
| **Diploma/Degree obtained, if any** | | | |
| Undergrad in 1983 and Masters in 1984 | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| New Trier West High School | | 1975-1979 | |
| **Address** | **City** | **State** | **Zip** |
| 7 Happ Road | Northfield | IL | 60093 |
| **Diploma/Degree obtained, if any** | | | |
| Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| N/A | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| N/A | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| N/A | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 2019 - Present | [redacted] Shoreline Ct | Glencoe | IL | 60022 |
| 2017 - 2019 | [redacted] Ardsley Road | Winnetka | IL | 60093 |
| 1999 - 2017 | [redacted] South Ridge Road | Lake Forest | IL | 60045 |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Medline Industries, LP formerly known as Medline Industries, Inc. | | 1986 - Current | |
| **Business Address** | **City** | **State** | **Zip** |
| Three Lakes Drive | Northfield | IL | 60093 |
| **Phone** | **Title** | | |
| 847-949-5500 | CEO | | |
| **Description of Duties** | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✓ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | ✓ | |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | ✓ | |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | ✓ | |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # 4,5,6. **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

See Attachment



Original Signature (electronic, copies or stamps not accepted)

9/15/22

Date

Applicant's initials CM

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Charles N. Mills

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/15/22

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Illinois, ss. County of Lake

I, Charles N. Mills, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

9/15/22

**Date**

Subscribed and Sworn to before me this 15 day of September 2022

Mary Nelson

**Notary Public Signature**

MARY NELSON
OFFICIAL SEAL
Notary Public, State of Illinois
My Commission Expires
March 16, 2025

**(Seal)**

Applicant's initials CM

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/13/2022)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of Pharmacy/MDEG/Wholesaler Medline Industries, LP

Pharmacy/MDEG/Wholesaler License # (if applicable) WH01636

Physical Address One Medline Place

City Mundelein State IL Zip 60060

Mailing Address (if different from physical address) Three Lakes Drive - 3D

City Northfield State IL Zip 60093

Telephone 847-949-5500 Website www.medline.com

Licensing Company Email ralicensing@medline.com

**Section 2: Personal Information**

First Michael Middle B Last Drazin

Alias(es, nicknames, name changes, etc.) Mike

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address Three Lakes Drive

City Northfield State IL Zip 60093

Telephone 847-949-5500 Email ralicensing@medline.com

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Northwestern University | | 2009-2010 | |
| **Address** | **City** | **State** | **Zip** |
| 633 Clark St | Evanston | IL | 60208 |
| **Diploma/Degree obtained, if any** | | | |
| Executive masters of Business Administration | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| University of Illinois, Urbana Champaign | | 1992 -1996 | |
| **Address** | **City** | **State** | **Zip** |
| 610 East John Street | Champaign | IL | 61820 |
| **Diploma/Degree obtained, if any** | | | |
| Bachelor of Science in Accountancy | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Peoria High School | | 1988-1992 | |
| **Address** | **City** | **State** | **Zip** |
| 1615 N. North St | Peoria | IL | 61604 |
| **Diploma/Degree obtained, if any** | | | |
| Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 06/20 - Present | [redacted]W Kingsley Dr. | Arlington Heights | IL | 60004 |
| 06/05 - 06/20 | [redacted]W. Ashford Lane | Arlington Heights | IL | 60004 |
| | | | | |
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**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Medline Industries, LP | | | 2018- Present | |
| **Business Address** | | **City** | **State** | **Zip** |
| Three Lakes Drive | | Northfield | IL | 60093 |
| **Phone** | **Title** | | | |
| 847-949-5500 | Chief Financial Officer | | | |

**Description of Duties**

Member of Executive Team, responsible for leading the Finance organization.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Illinois Tool Works | | | 2006-2017 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 155 Harlem Avenue | | Glenview | IL | 60025 |
| **Phone** | **Title** | | | |
| 224-661-8870 | Vice President Global FP&A and Invsetor Relations | | | |

**Description of Duties**

Communicate with existing and prospective investors, Simplify and enhance the Investor Relations strategy and reported directly to the Chief Financial Officer

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| N/A | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | | |
| | | | | |

**Description of Duties**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| N/A | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | | |
| | | | | |

**Description of Duties**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| N/A | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | | |
| | | | | |

**Description of Duties**

**Continue on next page if additional space is needed.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| N/A | | | |
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✓ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | ✓ | |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | ✓ | |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | ✓ | |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question #** 4,5,6 **. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

See Attached Disciplinary History

Original Signature (electronic, copies or stamps not accepted)

9/20/22
Date

Applicant's initials MD

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Michael B. Drazin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/20/22

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of ILLINOIS, ss. County of COOK

I, Michael B. Drazin, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

9/20/22

**Date**

Subscribed and Sworn to before me this 20 day of SEPT 2022.

**Notary Public Signature**

OFFICIAL SEAL
ADELWISA B DOMINGO
NOTARY PUBLIC - STATE OF ILLINOIS
MY COMMISSION EXPIRES:08/05/23

**(Seal)**

Applicant's initials MD

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/13/2022)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of Pharmacy/MDEG/Wholesaler Medline Industries, LP

Pharmacy/MDEG/Wholesaler License # (if applicable) WH01636

Physical Address One Medline Place

City Mundelein State IL Zip 60060

Mailing Address (if different from physical address) Three Lakes Drive - 3D

City Northfield State IL Zip 60093

Telephone 847-949-5500 Website www.medline.com

Licensing Company Email ralicensing@medline.com

**Section 2: Personal Information**

First James Middle D Last Abrams

Alias(es, nicknames, name changes, etc.) Jimmy

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address Three Lakes Drive

City Northfield State IL Zip 60093

Telephone 847-949-5500 Email ralicensing@medline.com

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| The University of Chicago Law School | | 1984-1987 | |
| **Address** | **City** | **State** | **Zip** |
| 1111 E 60th St | Chicago | IL | 60637 |
| **Diploma/Degree obtained, if any** | | | |
| Law Degree | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| The University of Michigan | | 1980-1984 | |
| **Address** | **City** | **State** | **Zip** |
| 500 S State Street | Ann Arbor | MI | 48109 |
| **Diploma/Degree obtained, if any** | | | |
| Bachelor of Arts Degree | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Highland Park High School | | 1976-1980 | |
| **Address** | **City** | **State** | **Zip** |
| 433 Vine Avenue | Highland Park | IL | 60032 |
| **Diploma/Degree obtained, if any** | | | |
| Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| over 10 years | [redacted] Sheridan Rd | Highland Park | IL | 60035 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Medline Industries, LP - formerly known as Medline Industries, Inc. | | | 1992 - Present |
| **Business Address** | **City** | **State** | **Zip** |
| Three Lakes Drive | Northfield | IL | 60093 |
| **Phone** | **Title** | | |
| 847-949-5500 | Chief Operating Officer | | |
| **Description of Duties** | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✓ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | ✓ | |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | ✓ | |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | ✓ | |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # 4,5,6. **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

See Attachment

Original Signature (electronic, copies or stamps not accepted)

9/15/22
Date

Applicant's initials JDA

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

James D. Abrams

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/15/22

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Illinois, ss. County of Lake

I, James D Abrams, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

9/15/22

**Date**

Subscribed and Sworn to before me this 15 day of September 2022

**Notary Public Signature**

MARY NELSON
OFFICIAL SEAL
Notary Public, State of Illinois
My Commission Expires
March 18, 2025

**(Seal)**

Applicant's initials JDA

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/13/2022)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of Pharmacy/MDEG/Wholesaler Medline Industries, LP

Pharmacy/MDEG/Wholesaler License # (if applicable) WH01636

Physical Address One Medline Place

City Mundelein State IL Zip 60060

Mailing Address (if different from physical address) Three Lakes Drive - 3D

City Northfield State IL Zip 60093

Telephone 847-949-5500 Website www.medline.com

Licensing Company Email ralicensing@medline.com

**Section 2: Personal Information**

First Andrew Middle J Last Mills

Alias(es, nicknames, name changes, etc.) Andy

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address Three Lakes Drive - 3D

City Northfield State IL Zip 60093

Telephone 847-949-5500 Email ralicensing@medline.com

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| J.L. Kellogg School of Management at Northwestern University | | 1983-1985 | |
| **Address** | **City** | **State** | **Zip** |
| 2211 Campus Dr. | Evanston | IL | 60208 |
| Diploma/Degree obtained, if any | | | |
| MBA | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Tulane University | | 1979 - 1983 | |
| **Address** | **City** | **State** | **Zip** |
| 6823 St. Charles Avenue | New Orleans | LA | 70118 |
| Diploma/Degree obtained, if any | | | |
| Bachelor of Science | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| over 10 years | [redacted] Woodbridge Ln | Highland Park | IL | 60035 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Medline Industries, LP - formerly known as Medline Industries, Inc. | | 1992 - Current | |
| **Business Address** | **City** | **State** | **Zip** |
| Three Lakes Drive | Northfield | IL | 60093 |
| **Phone** | **Title** | | |
| 947-949-5500 | President | | |
| **Description of Duties** | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| N/A | | | | |
| Business Address | | City | State | Zip |
| Phone | Title | | | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| Phone | Title | | | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| Phone | Title | | | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| Phone | Title | | | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| Phone | Title | | | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✓ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | ✓ | |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | ✓ | |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | ✓ | |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question #** 4,5,6 **. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

See Attachment

Original Signature (electronic, copies or stamps not accepted)

9/15/22
Date

Applicant's initials AM

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Andrew J. Mills

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/15/22

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Illinois, ss. County of Lake

I, Andrew J . Mills, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

9/15/22

**Date**

Subscribed and Sworn to before me this 15 day of September 2022

**Notary Public Signature**

MARY NELSON
OFFICIAL SEAL
Notary Public, State of Illinois
My Commission Expires
March 16, 2025

(Seal)

Applicant's initials AM

Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093
1 847 949 5500
1 800 MEDLINE (633 5463)
medline.com

September 22, 2020

List of Facilities for Nevada State Board of Pharmacy Bond No. 105625536

| | | |
|---|---|---|
| B01- | Medline Industries, Inc. – | **One Medline Place, Mundelein, IL 60060** |
| B02- | Medline Industries, Inc. – | **1501 Harris Road, Libertyville, IL 60048** |
| B49- | Medline Industries, Inc. – | **42500 Winchester Road, Temecula, CA 92590** |
| B71- | Medline Industries, Inc. – | **1820 S 5200 W, Salt Lake City, UT 84104** |
| C09- | Medline Industries, Inc. – | **1960 W Miro Way, Rialto, CA 92376** |
| C46 – | Medline Industries, Inc. – | **5701 Promontory Parkway, Ste 100, Tracy, CA 95377** |
| C50 – | Medline Industries, Inc.- | **8787 W Buckeye Rd, Tolleson, AZ 85353** |
| C75- | Medline Industries, Inc. – | **3770 Hogum Bay Road NE, Lacey, WA 98516** |
| MXC- | Medline Industries, Inc.- | **16415 Cosmos St, Moreno Valley, CA 92551** |

# GENERAL SURETY RIDER

To be attached and form a part of

| | |
|---|---|
| Bond No. | 107285092 |
| For | Pharmaceutical Wholesaler Bond |
| Dated effective | 08/06/2020 (MONTH, DAY, YEAR) |
| Executed by | Medline Industries, LP., as Principal, (PRINCIPAL) |
| And by | Travelers Casualty and Surety Company of America, as Surety, (SURETY) |
| And in favor of | Nevada State Board of Pharmacy (OBLIGEE) |

**In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing**

| INFORMATION | FROM | TO |
|---|---|---|
| Principal Name | Medline Industries, Inc. | Medline Industries, LP. |

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

**This rider is effective** **12/16/2021**

**(MONTH, DAY, YEAR)**

**Signed and Sealed** **12/16/2021**

**(MONTH, DAY, YEAR)**

**Travelers Casualty and Surety Company of America**

**SURETY**

**BY**

**Peter S. Forker, ATTORNEY-IN-FACT**

TRAVELERS

**Travelers Casualty and Surety Company of America**
**Travelers Casualty and Surety Company**
**St. Paul Fire and Marine Insurance Company**

## POWER OF ATTORNEY

**KNOW ALL MEN BY THESE PRESENTS**: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint **Peter S Forker** of **ROLLING MEADOWS**, **Illinois**, their true and lawful Attorney(s)-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

**IN WITNESS WHEREOF**, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **21st** day of **April**, **2021**.

State of Connecticut

City of Hartford ss.

By: _____
Robert L. Raney, Senior Vice President

On this the **21st** day of **April**, **2021**, before me personally appeared **Robert L. Raney**, who acknowledged himself to be the Senior Vice President of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

**IN WITNESS WHEREOF**, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June**, **2026**

_____
Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

**RESOLVED,** that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

**FURTHER RESOLVED,** that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

**FURTHER RESOLVED,** that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

**FURTHER RESOLVED,** that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this 16th day of December 2021

_____
Kevin E. Hughes, Assistant Secretary

***To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.***
***Please refer to the above-named Attorney(s)-in-Fact and the details of the bond to which this Power of Attorney is attached.***

## ACKNOWLEDGMENT BY SURETY

STATE OF Illinois }
County of Lake } ss.

On this 16th day of December, 2021, before me personally appeared Peter S. Forker, known to, me to be the Attorney-in-Fact of Travelers Casualty and Surety Company of America, the corporation that executed the within instrument, and acknowledged to me that such corporation executed the same.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal, at my office in the aforesaid County, the day and year in this certificate first above written.

OFFICIAL SEAL
REBECCA M JOHLIE
NOTARY PUBLIC, STATE OF ILLINOIS
My Commission Expires 9/22/24

Notary Public in the State of Illinois
County of Lake

# GENERAL SURETY RIDER

**To be attached and form a part of:**

**Type of Bond:** License & Permit

**Bond No. :** 105625536

**Dated effective:** 7/20/2011
(MONTH, DAY, YEAR)

**Executed by:** Medline Industries, Inc. , **as Principal,**
(PRINCIPAL)

**and by:** Travelers Casualty and Surety Company of America , **as Surety,**
(SURETY)

**and in favor of :** Nevada State Board of Pharmacy .
(OBLIGEE)

**In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to Add to and attach Schedule of Facilities to Bond No. 105625536**

**Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.**

**This rider is effective** 7/20/2020
(MONTH, DAY, YEAR)

**Signed and Sealed** 9/22/2020
(MONTH, DAY, YEAR)

Travelers Casualty and Surety Company of America
SURETY

BY: _____
Peter S. Forker, ATTORNEY-IN-FACT

TRAVELERS

**Travelers Casualty and Surety Company of America**
**Travelers Casualty and Surety Company**
**St. Paul Fire and Marine Insurance Company**

## POWER OF ATTORNEY

**KNOW ALL MEN BY THESE PRESENTS**: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint **Peter S. Forker** of **Rolling Meadows, Illinois**, their true and lawful Attorney-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

**IN WITNESS WHEREOF**, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **3rd** day of **February, 2017.**

State of Connecticut

City of Hartford ss.

By: _____
Robert L. Raney, Senior Vice President

On this the **3rd** day of **February, 2017**, before me personally appeared **Robert L. Raney**, who acknowledged himself to be the Senior Vice President of Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

**In Witness Whereof**, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June, 2021**

Marie C. Tetreault
Marie C. Tetreault, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company, which resolutions are now in full force and effect, reading as follows:

**RESOLVED**, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

**FURTHER RESOLVED**, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

**FURTHER RESOLVED**, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

**FURTHER RESOLVED**, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this 22nd day of September 2020.

Kevin E. Hughes
Kevin E. Hughes, Assistant Secretary

***To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.***
***Please refer to the above-named Attorney-in-Fact and the details of the bond to which the power is attached.***

# VERIFICATION CERTIFICATE FOR INDEFINITE TERM SURETY BOND

---

**THIS IS TO CERTIFY that Bond No. 105625536 issued by Travelers Casualty and Surety Company of America dated this 20 day of July , 2011, in the amount of One Hundred Thousand Dollars and 00/100 Dollars ($100,000.00), on behalf of Medline Industries, Inc. (as Principal), and in favor of Nevada State Board of Pharmacy (as Obligee) , covers a term which began on the 20 day of July , 2015, and ends only with the cancellation of said bond or other legal termination thereof; and that the said bond remains in effect, subject to all its agreements, conditions and limitations.**

**Signed, sealed and dated* (enter below)**

**Travelers Casualty and Surety Company of America**

**BY** _____
Peter S. Forker
**Attorney-in-Fact**

**09/22/2020**
***Use current or renewal date.**

---

TRAVELERS

**Travelers Casualty and Surety Company of America**
**Travelers Casualty and Surety Company**
**St. Paul Fire and Marine Insurance Company**

## POWER OF ATTORNEY

**KNOW ALL MEN BY THESE PRESENTS**: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint **Peter S. Forker** of **Rolling Meadows**, **Illinois**, their true and lawful Attorney-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

**IN WITNESS WHEREOF**, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **3rd** day of **February**, **2017**.

State of Connecticut

City of Hartford ss.

By: _____
Robert L. Raney, Senior Vice President

On this the **3rd** day of **February**, **2017**, before me personally appeared **Robert L. Raney**, who acknowledged himself to be the Senior Vice President of Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

**In Witness Whereof**, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June**, **2021**

Marie C. Tetreault
Marie C. Tetreault, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company, which resolutions are now in full force and effect, reading as follows:

**RESOLVED**, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

**FURTHER RESOLVED**, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

**FURTHER RESOLVED**, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

**FURTHER RESOLVED**, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this 22nd day of September 2020

Kevin E. Hughes
Kevin E. Hughes, Assistant Secretary

***To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.***
***Please refer to the above-named Attorney-in-Fact and the details of the bond to which the power is attached.***

# GENERAL SURETY RIDER

To be attached and form a part of

| | |
|---|---|
| Bond No. | 105625536 |
| For | Pharmaceutical Wholesaler Surety Bond |
| Dated effective | 07/20/2015 (MONTH, DAY, YEAR) |
| Executed by | Medline Industries, LP., as Principal, (PRINCIPAL) |
| And by | Travelers Casualty and Surety Company of America, as Surety, (SURETY) |
| And in favor of | Nevada State Board of Pharmacy (OBLIGEE) |

**In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing**

| INFORMATION | FROM | TO |
|---|---|---|
| Principal Name | Medline Industries, Inc. | Medline Industries, LP. |
| | | |

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

**This rider is effective** **12/16/2021**

**(MONTH, DAY, YEAR)**

**Signed and Sealed** **12/16/2021**

**(MONTH, DAY, YEAR)**

**Travelers Casualty and Surety Company of America**

**SURETY**

**BY**

**Peter S. Forker, ATTORNEY-IN-FACT**

TRAVELERS

**Travelers Casualty and Surety Company of America**
**Travelers Casualty and Surety Company**
**St. Paul Fire and Marine Insurance Company**

## POWER OF ATTORNEY

**KNOW ALL MEN BY THESE PRESENTS**: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint **Peter S Forker** of **ROLLING MEADOWS**, **Illinois**, their true and lawful Attorney(s)-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

**IN WITNESS WHEREOF**, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **21st** day of **April, 2021**.

State of Connecticut

City of Hartford ss.

By: _____
Robert L. Raney, Senior Vice President

On this the **21st** day of **April, 2021**, before me personally appeared **Robert L. Raney**, who acknowledged himself to be the Senior Vice President of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

**IN WITNESS WHEREOF**, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June, 2026**

_____
Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

**RESOLVED,** that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

**FURTHER RESOLVED,** that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

**FURTHER RESOLVED,** that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

**FURTHER RESOLVED,** that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this 16th day of December 2024

_____
Kevin E. Hughes, Assistant Secretary

***To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.***
***Please refer to the above-named Attorney(s)-in-Fact and the details of the bond to which this Power of Attorney is attached.***

## ACKNOWLEDGMENT BY SURETY

STATE OF Illinois }
County of Lake } ss.

On this 16th day of December, 2021, before me personally appeared Peter S. Forker, known to, me to be the Attorney-in-Fact of Travelers Casualty and Surety Company of America, the corporation that executed the within instrument, and acknowledged to me that such corporation executed the same.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal, at my office in the aforesaid County, the day and year in this certificate first above written.

OFFICIAL SEAL
REBECCA M JOHLIE
NOTARY PUBLIC, STATE OF ILLINOIS
My Commission Expires 9/22/24

Notary Public in the State of Illinois
County of Lake

# 4N

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

**Non-Refundable $1,000 Fee**

Rev (08/17/2022)

| Where is the facility located? | | ☐ Nevada ■ Out-of-State |
|---|---|---|
| **Type of Application (check applicable box)** | | **Wholesaler Business Type (check applicable box)** |
| ■ New Wholesaler<br>☐ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH _____ | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>■ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: Neotech Products LLC

Physical Address: 28430 Witherspoon Parkway

City: Valencia State: CA Zip: 91355

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (661) 775-7466 Website: neotechproducts.com

Name of Designated Representative (DR): Craig McCrary

Licensing Company Email: _____ DR Email: craig@neotechproducts.com

| Entities the Wholesaler will Serve (✓ all applicable) | Products to be Handled or Wholesaled (✓ all applicable) | Type of Wholesaling (✓ all applicable) |
|---|---|---|
| ☐ Pharmacies | ☐ Dangerous Drugs | ■ Manufacturer |
| ☐ Practitioners | ☐ Controlled Substances | ☐ Repacker |
| ☐ Hospitals | ■ *Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ■ Wholesalers | ☐ Others: | ☐ Warehouse |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ☐ Others: | | ☐ Others: |

| Section 2: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✓ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | ✓ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | ✓ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✓ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question #** N/A **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| N/A | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| **Reason/Charge** | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| **Name of Business/Industry/Entity** | | | | |

**Provide explanation below:**

G McG

Original Signature (electronic, copies or stamps not accepted)

4/6/2023

Date

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: N/A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

**Section 4: Publicly Traded Corporation**

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: N/A

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

**Section 6: Partnership**

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

**Section 7: Sole Owner**

Owner's Name: BEAT CAL LLC (Beat Cal holding . LLC )

Business Name: Neotech Products

Business Address: 28430 Witherspoon Parkway

City: Valenica State: CA Zip: 91355

Telephone: 661.775.7466 Email: RA@neotechproducts.com

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | ✓ |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | ✓ | |
| 1. Copy of FDA registration<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** | | ✓ | | |
| • **List of all partners and their percent ownership.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** | ✓ | ✓ | ✓ | ✓ NA |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** | ✓ | ✓ | ✓ | ✓ |
| • ***Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ | ✓ | ✓ | ✓ | ✓ |
| • **If providing *Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ 25 |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Neotech Products LLC

Facility Name

Craig McCrary

Print Name of Authorized Person Submitting Application

CMcC

Original signature of Authorized Person (copies or stamps not accepted)

4/6/23

Date

| Board Use Only | Date Received: 5-1-23 | Amount: 1000.00 CC |
|---|---|---|

## Barbara Blackburn

**From:** Juan Bulnes <juancarlos@neotechproducts.com>
**Sent:** Wednesday, May 10, 2023 11:57 AM
**To:** Barbara Blackburn
**Cc:** Maria Herrera
**Subject:** RE: Neotech Products LLC
**Attachments:** 8. 2023-05-01 Executed Final Bond #100078400 - Surety Bond.pdf; 9. Credit Card form.pdf

**Importance:** High

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Good morning,

I hope this email finds you well,

Per you requested, please see the attached missing documents.

Regarding the list of officers that you are requesting, we have only Craig McCrary as our designated rep. (President)

Best regards,

**Juan Carlos Bulnes**
Quality Assurance Associate

**Tel** (800) 966-0500 Ext. 136
**Fax** (661) 775-7464
**Website** neotechproducts.com






**From:** Barbara Blackburn <bblackburn@pharmacy.nv.gov>
**Sent:** Monday, May 1, 2023 1:18 PM
**To:** Craig McCrary <craig@neotechproducts.com>
**Cc:** Maria Herrera <m.herrera@pharmacy.nv.gov>
**Subject:** Neotech Products LLC
**Importance:** High

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

# STATE OF CALIFORNIA

## DEPARTMENT OF PUBLIC HEALTH
## FOOD AND DRUG BRANCH

## MEDICAL DEVICE MANUFACTURING LICENSE

Neotech Products, LLC
28430 Witherspoon Pkwy
Valencia, CA 91355

**LICENSE NUMBER: 96648**
**EXPIRATION DATE: 5/2/2024**

The person named herein is licensed to manufacture devices through the expiration date of this license. This license is issued in accordance with the provisions of Division 104, Chapter 6, Article 6 of the California Health and Safety Code and is not transferable to any other person or place. The licensee is required by law to immediately notify the California Department of Public Health of any change in the information reported in the application.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

# Secretary of State
## Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

| | |
|---|---|
| **Entity Name:** | NEOTECH PRODUCTS LLC |
| **Entity No.:** | 201709510259 |
| **Registration Date:** | 04/23/1987 |
| **Entity Type:** | Limited Liability Company - CA |
| **Formed In:** | CALIFORNIA |
| **Status:** | Active |

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

**IN WITNESS WHEREOF**, I execute this certificate and affix the Great Seal of the State of California this day of April 20, 2023.

**SHIRLEY N. WEBER, PH.D.**
**Secretary of State**

**Certificate No.:** 101806820

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **bizfileOnline.sos.ca.gov**.

ACORD

# CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 4/10/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Arthur J. Gallagher Risk Management Services, LLC
21820 Burbank Boulevard
Suite 301
Woodland Hills CA 91367

License#: 0D69293

CONTACT NAME: Vanessa Aldershof
PHONE (A/C, No, Ext): 818-449-0216 FAX (A/C, No): 818-316-0990
E-MAIL ADDRESS: Vanessa_Aldershof@ajg.com

| INSURER(S) AFFORDING COVERAGE | NAIC # |
|---|---|
| INSURER A : Travelers Property Casualty Co of America | 25674 |
| INSURER B : The Travelers Indemnity Company of CT | 25682 |
| INSURER C : | |
| INSURER D : | |
| INSURER E : | |
| INSURER F : | |

INSURED
Neotech Products LLC
28430 Witherspoon Parkway
Valencia CA 91355

NEOTPRO-01

**COVERAGES** **CERTIFICATE NUMBER: 1786128551** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

| INSR LTR | TYPE OF INSURANCE | ADDL INSD | SUBR WVD | POLICY NUMBER | POLICY EFF (MM/DD/YYYY) | POLICY EXP (MM/DD/YYYY) | LIMITS | |
|---|---|---|---|---|---|---|---|---|
| A | X COMMERCIAL GENERAL LIABILITY | | | 6307K775733 | 4/1/2023 | 4/1/2024 | EACH OCCURRENCE | $ 1,000,000 |
| | [ ] CLAIMS-MADE [X] OCCUR | | | | | | DAMAGE TO RENTED PREMISES (Ea occurrence) | $ 300,000 |
| | | | | | | | MED EXP (Any one person) | $ 10,000 |
| | | | | | | | PERSONAL & ADV INJURY | $ 1,000,000 |
| | GEN'L AGGREGATE LIMIT APPLIES PER: | | | | | | GENERAL AGGREGATE | $ 2,000,000 |
| | [ ] POLICY [ ] PRO-JECT [ ] LOC | | | | | | PRODUCTS - COMP/OP AGG | $ Excluded |
| | [ ] OTHER: | | | | | | | $ |
| B | AUTOMOBILE LIABILITY | | | BABM689740 | 4/1/2023 | 4/1/2024 | COMBINED SINGLE LIMIT (Ea accident) | $ 1,000,000 |
| | [ ] ANY AUTO | | | | | | BODILY INJURY (Per person) | $ |
| | [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS | | | | | | BODILY INJURY (Per accident) | $ |
| | [X] HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY | | | | | | PROPERTY DAMAGE (Per accident) | $ |
| | | | | | | | | $ |
| A | X UMBRELLA LIAB [X] OCCUR | | | CUP7K804339 | 4/1/2023 | 4/1/2024 | EACH OCCURRENCE | $ 3,000,000 |
| | [ ] EXCESS LIAB [ ] CLAIMS-MADE | | | | | | AGGREGATE | $ 3,000,000 |
| | [ ] DED [ ] RETENTION $ | | | | | | | $ |
| A | WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N | | | UB7K795559 | 4/1/2023 | 4/1/2024 | X PER STATUTE [ ] OTH-ER | |
| | ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [ ] (Mandatory in NH) | N / A | | | | | E.L. EACH ACCIDENT | $ 1,000,000 |
| | If yes, describe under DESCRIPTION OF OPERATIONS below | | | | | | E.L. DISEASE - EA EMPLOYEE | $ 1,000,000 |
| | | | | | | | E.L. DISEASE - POLICY LIMIT | $ 1,000,000 |
| A | Product Liability<br>Claims Made<br>Ded: $25,000 | | | ZPP51M97475 | 4/1/2023 | 4/1/2024 | Aggregate<br>Retro Date | $10,000,000<br>11/1/1998 |

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

**CERTIFICATE HOLDER**

Evidence of Insurance Coverage

**CANCELLATION**

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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17-327992

# Secretary of State
# Statement of Information
# (Limited Liability Company)

**LLC-12**

**FILED**
Secretary of State
State of California
APR 05 2017

IMPORTANT — Read instructions before completing this form.

Filing Fee - $20.00

Copy Fees – Face Page $1.00 & .50 for each attachment page;
Certification Fee - $5.00

127

This Space For Office Use Only

**1. Limited Liability Company Name**
Neotach Products LLC

**2. 12-Digit Secretary of State File Number**
201709510259

**3. State or Place of Organization (only if formed outside of California)**
California

**4. Business Addresses**

| | City (no abbreviations) | State | Zip Code |
|---|---|---|---|
| a. Street Address of Principal Office - Do not list a P.O. Box: 28430 WITHERSPOON PARKWAY | VALENCIA | CA | 91355 |
| b. Mailing Address of LLC, if different than item 4a | | | |
| c. Street Address of California Office, if Item 4a is not in California - Do not list a P.O. Box | | CA | |

**5. Manager(s) or Member(s)**
If no managers have been appointed or elected, provide the name and address of each member. At least one name and address must be listed. If the manager/member is an individual, complete items 5a and 5c (leave item 5b blank). If the manager/member is an entity, complete items 5b and 5c (leave item 5a blank). Note: The LLC cannot serve as its own manager or member. If the LLC has additional managers/members, enter the name(s) and addresses on Form LLC-12A (see instructions).

| | Middle Name | Last Name | Suffix |
|---|---|---|---|
| a. First Name, if an individual - Do not complete item 5b: Arnold | | Heyman | M.D. |
| b. Entity Name - Do not complete item 5a | | | |

| | City (no abbreviations) | State | Zip Code |
|---|---|---|---|
| c. Address: 28430 WITHERSPOON PARKWAY | VALENCIA | CA | 91355 |

**6. Agent for Service of Process**
Item 6a and 6b: If the agent is an individual, the agent must reside in California and Item 6a and 6b must be completed with the agent's name and California address. Item 6c: If the agent is a California Registered Corporate Agent, a current agent registration certificate must be on file with the California Secretary of State and Item 6c must be completed (leave Item 6a-6b blank).

| | Middle Name | Last Name | Suffix |
|---|---|---|---|
| a. California Agent's First Name (if agent is not a corporation): Arnold | | Heyman | M.D. |
| b. Street Address (if agent is not a corporation) - Do not list a P.O. Box: 28430 WITHERSPOON PARKWAY | City (no abbreviations): VALENCIA | State: CA | Zip Code: 91355 |
| c. California Registered Corporate Agent's Name (if agent is a corporation) – Do not complete item 6a or 6b | | | |

**7. Type of Business**
a. Describe the type of business or services of the Limited Liability Company: Healthcare products

**8. Chief Executive Officer, if elected or appointed**

| | Middle Name | Last Name | Suffix |
|---|---|---|---|
| a. First Name | | | |
| b. Address | City (no abbreviations) | State | Zip Code |

**9. The information contained herein, including any attachments, is true and correct.**

4/4/2017 — Arnold Heyman M.D. — Manager

Date — Type or Print Name of Person Completing the Form — Title — Signature

**Return Address (Optional)** (For communication from the Secretary of State related to this document, or if purchasing a copy of the filed document enter the name of a person or company and the mailing address. This information will become public when filed. SEE INSTRUCTIONS BEFORE COMPLETING.)

Name:
Company:
Address:
City/State/Zip:

LLC-12 (REV 07/2016)

2016 California Secretary of State
www.sos.ca.gov/business/be

FDA

FDA Home[3] Medical Devices[4] Databases[5]

## Establishment Registration & Device Listing

New Search | Back To Search Results

**Establishment:**
NEOTECH PRODUCTS, LLC
28430 Witherspoon Pkwy
Valencia, CA 91355
**Registration Number:** 2025917
**FEI Number*:** 2025917
**Status:** Active
**Date Of Registration Status:** 2023

**Owner/Operator:**
Neotech Products LLC[6]
28430 Witherspoon Parkway
Valencia, CA US 91355
**Owner/Operator Number:** 2025917[7]

**Official Correspondent:**
Leo H Arya
28430 Witherspoon Pkw
Valencia, CA 91355
**Phone:** 001-661-7757466-126

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2025917&OwnerOperator

Page Last Updated: 05/01/2023

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7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2025917&OwnerOperator

| Neotech's Employees List | |
|---|---|
| Order | Full name |
| 1 | Abrahms, Nicholas |
| 2 | Arya, Leo |
| 3 | Behan, Jane U |
| 4 | Beltran, Yessenia V |
| 5 | Bonnet, Aaron |
| 6 | Bulnes, Juan C |
| 7 | Cavazos, Ernesto |
| 8 | Ceniza, Neil |
| 9 | Cevallos, Ornella |
| 10 | Cojulun, Lidia |
| 11 | Crayon, Allyson |
| 12 | Dalire, Stephanie R |
| 13 | Dimmitt, Sara |
| 14 | Duran, Antonio |
| 15 | Elman, Daniel M |
| 16 | Estela, Susana |
| 17 | Flores, Talia |
| 18 | Garcia, Consuelo |
| 19 | Garcia, Janette |
| 20 | Gonzalez, Gloria L |
| 21 | Gonzalez, Petra I |
| 22 | Green, Jennifer C |
| 23 | Hafeznezami, Hamidreza |
| 24 | Hellstrom, Nora |
| 25 | Keirn, Steven |
| 26 | Llamas-Wittmer, Julia |
| 27 | Lopez Perez, Oveld A |
| 28 | Macias, Martha |
| 29 | Mahajan, Afshin B |
| 30 | McCrary, Craig |
| 31 | McCrary, Judy |

| Neotech's Employees List | |
|---|---|
| Order | Full name |
| 32 | Meraz, Maria Lourdes |
| 33 | Mondragon, Joey |
| 34 | Navarrete, Cinthia |
| 35 | Orjuela, Hector E |
| 36 | Oviedo, Shila M |
| 37 | Penuelas, Raquel L |
| 38 | Pirehpour, David J |
| 39 | Portillo, Maria |
| 40 | Rodriguez, Karina |
| 41 | Rosales, Stephanie |
| 42 | Santiago, Sylvia |
| 43 | Scott, Brianne R |
| 44 | Scott, Perla D |
| 45 | Seibt, Sarah M |
| 46 | Stanislawski, Josie A |
| 47 | Tambunting, Laken |
| 48 | Tejeda, Brenda |
| 49 | Tobar, Maria T |
| 50 | Torres, Guadalupe |
| 51 | Torres, Juan J |
| 52 | Torres, Raymond J |
| 53 | Torres, Thomas A |
| 54 | Trejo, Libertad |
| 55 | Turcios, Delma |
| 56 | Velds, Hunter G |
| 57 | Votruba, Angela |
| 58 | Windsor, Steve |
| 59 | Young, Karen |
| 60 | Zayas Castro, Maribel |
| 61 | Zayas, Brian |

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

### Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Neotech Products LLC

Pharmacy/Wholesaler License # (if applicable): FDA# 2025917

Physical Address: 28430 Witherspoon Parkway

City: Valencia State: CA Zip: 91355

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: (661) 775-7466 Website: www.neotechproducts.com

Licensing Company Email:

### Section 2: Personal Information

First: Craig Middle: Ryan Last: McCrary

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: 28430 Witherspoon Parkway

City: Valencia State: CA Zip: 91355

Telephone: (661) 775-7466 Email: craig@neotechproducts.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✔ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Aragon High School | | 1979-1983 | |
| **Address** | **City** | **State** | **Zip** |
| 900 Alameda De Las Pulgas | San Mateo | CA | 94402 |
| Diploma/Degree obtained, if any | | | |
| Graduated | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| San Diego State University | | 1985-1989 | |
| **Address** | **City** | **State** | **Zip** |
| 5500 Campanile Dr | San Diego | CA | 92182 |
| Diploma/Degree obtained, if any | | | |
| Health Science & Health Education Studies | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 1190 - Present | [redacted] Conde Dr | Valencia | CA | 91354 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Neotech Products LLC | | | 1990 - Present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 28430 Witherspoon Parkway | | Valencia | CA | 91355 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 661.775.7466 | President | | Over 30 Years | |
| **Description of Duties** | | | | |
| Overseeing the entire business and all related activities | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✔ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # N/A . Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

C M^c C

Original Signature (electronic, copies or stamps not accepted)

4/27/23

Date

I, Craig McCrary, **certify that as the designated representative for**

Neotech Products LLC,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. CM I am at least 21 years of age;
3. CM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Craig McCrary

Print Name (First, Last)

CMcG

Original Signature (electronic, copies or stamps not accepted)

4/27/23

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Craig McCrary

Print Name (First, Last)

CMcC

Original Signature (electronic, copies or stamps not accepted)

4/27/23

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

**Date**

Subscribed and Sworn to before me this _____ day of _____.

**Notary Public Signature**

*See attached

N.P.

(Seal)

**CALIFORNIA JURAT WITH AFFIANT STATEMENT** **GOVERNMENT CODE § 8202**

☑ See Attached Document (Notary to cross out lines 1–6 below)
☐ See Statement Below (Lines 1–6 to be completed only by document signer[s], not Notary)

1
2
3
4
5
6

*Signature of Document Signer No. 1* *Signature of Document Signer No. 2 (if any)*

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Los Angeles

Subscribed and sworn to (or affirmed) before me

on this 27 day of April, 2023.
by *Date* *Month* *Year*

(1) Craig McCrary

(and (2) _____),
*Name(s) of Signer(s)*

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

DANIELLE GILLY
COMM. #2433084
Notary Public - California
LOS ANGELES COUNTY
My Comm. Exp. Jan. 1, 2027

*Place Notary Seal and/or Stamp Above*

Signature _____
*Signature of Notary Public*

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# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

### Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Neotech Products LLC, Craig McCrary, President — MDEG License # (if applicable): FDA# 2025917

Physical Address: 28430 Witherspoon Parkway

City: Valencia — State: CA — Zip: 91355

Mailing Address (if different from physical address):

City: — State: — Zip:

Telephone: (661) 775-7466 — Website: neotechproducts.com

Licensing Company Email:

### Section 2: Personal Information

First: Craig — Middle: RYAN — Last: McCrary

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☑ M ☐ F ☐ X

Mailing Address: 28430 Witherspoon Parkway

City: Valencia — State: CA — Zip: 91355

Telephone: 661.775.7466 — Email: Craig@neotechproducts.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✓ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | From - To (MM/YY – MM/YY) | | |
|---|---|---|---|
| ARAGON HIGH SCHOOL | 1979 - 1983 | | |
| **Address** | **City** | **State** | **Zip** |
| 900 ALAMEDA DE LAS PULGAS | SAN MATEO | CA | 94402 |
| **Diploma/Degree obtained, if any** | | | |
| GRADUATED | | | |

| School Name | From - To (MM/YY – MM/YY) | | |
|---|---|---|---|
| SAN DIEGO STATE UNIVERSITY | 1985 - 1989 | | |
| **Address** | **City** | **State** | **Zip** |
| 5500 CAMPANILE DR | SAN DIEGO | CA | 92182 |
| **Diploma/Degree obtained, if any** | | | |
| HEALTH SCIENCE & HEALTH EDUCATION STUDIES | | | |

| School Name | From - To (MM/YY – MM/YY) | | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | From - To (MM/YY – MM/YY) | | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | From - To (MM/YY – MM/YY | | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 1990 - PRESENT | [redacted] CONDE DR | VALENCIA | CA | 91354 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Neotech Products | | | 1990- Present |
| **Business Address** | **City** | **State** | **Zip** |
| 28430 Witherspoon Parkway | Valencia | CA | 91355 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| 661.775.7466 | President | Over 30 years | |
| **Description of Duties** | | | |
| Overseeing the entire business and all related activities. | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| N/A | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| N/A | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| N/A | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| N/A | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

N/A

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

N/A

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

N/A

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

N/A

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

N/A

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state? | | ✓ |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline. | | ✓ |

**Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # N/A. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| N/A | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

4/6/2023
Date

I, McCrary, certify that as the MDEG Administrator for

_____,

that I (initial that you have read and meet the following requirements):

1. X Have a high school diploma or its equivalent;
2. X Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. X Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. X Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Craig McCrary
Print Name (First, Last)

CGM
Original Signature (electronic, copies or stamps not accepted)

4/6/2023
Date

| Board Use Only | Date Received: 5-4-23 |
|---|---|

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/13/2022)

### Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Neotech Products LLC

Pharmacy/MDEG/Wholesaler License # (if applicable): FDA# 2025917

Physical Address: 28430 Witherspoon Parkway

City: Valencia State: CA Zip: 91355

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: (661) 775-7466 Website: www.neotechproducts.com

Licensing Company Email:

### Section 2: Personal Information

First: Craig Middle: Ryan Last: McCrary

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: 28430 Witherspoon Parkway

City: Valencia State: CA Zip: 91355

Telephone: (661) 775-7466 Email: craig@neotechproducts.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✔ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Aragon High School | | 1979 - 1983 | |
| **Address** | **City** | **State** | **Zip** |
| 900 Alameda De Las Pulgas | San Mateo | CA | 94402 |
| **Diploma/Degree obtained, if any** | | | |
| Graduated | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| San Diego Sate University | | 1985 - 1989 | |
| **Address** | **City** | **State** | **Zip** |
| 5500 Campanile Dr | San Diego | CA | 92182 |
| **Diploma/Degree obtained, if any** | | | |
| Health Science & Health Education Studies | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 1990 - Present | [redacted] Conde Dr | Valencia | CA | 91354 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| | | | | |
|---|---|---|---|---|
| Business Name: Neotech Products LLC | | | | From - To (MM/YY – MM/YY): 1990 - Present |
| Business Address: 28430 Witherspoon Parkway | | City: Valencia | State: CA | Zip: 91355 |
| Phone: 661.775.7466 | Title: President | | | |
| Description of Duties: Overseeing the entire business and all related activities | | | | |
| Business Name | | | | From - To (MM/YY – MM/YY) |
| Business Address | | City | State | Zip |
| Phone | Title | | | |
| Description of Duties | | | | |
| Business Name | | | | From - To (MM/YY – MM/YY) |
| Business Address | | City | State | Zip |
| Phone | Title | | | |
| Description of Duties | | | | |
| Business Name | | | | From - To (MM/YY – MM/YY) |
| Business Address | | City | State | Zip |
| Phone | Title | | | |
| Description of Duties | | | | |
| Business Name | | | | From - To (MM/YY – MM/YY) |
| Business Address | | City | State | Zip |
| Phone | Title | | | |
| Description of Duties | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✔ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # N/A . Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

C. McG

Original Signature (electronic, copies or stamps not accepted)

4/27/23

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Craig McCrary

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/27/23

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

**Date**

Subscribed and Sworn to before me this _____ day of _____.

**Notary Public Signature**

*See attached

, N.P.

(Seal)

**CALIFORNIA JURAT WITH AFFIANT STATEMENT** **GOVERNMENT CODE § 8202**

☑ See Attached Document (Notary to cross out lines 1–6 below)
☐ See Statement Below (Lines 1–6 to be completed only by document signer[s], not Notary)

1
2
3
4
5
6

*Signature of Document Signer No. 1* *Signature of Document Signer No. 2 (if any)*

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Los Angeles

Subscribed and sworn to (or affirmed) before me

on this 27 day of April, 2023.
by *Date* *Month* *Year*

(1) Craig McCrary

(and (2) _____).
*Name(s) of Signer(s)*

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

DANIELLE GILLY
COMM. #2433094
Notary Public - California
LOS ANGELES COUNTY
My Comm. Exp. Jan. 1, 2027

*Place Notary Seal and/or Stamp Above*

Signature _____
*Signature of Notary Public*

**OPTIONAL**

*Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.*

**Description of Attached Document**

Title or Type of Document: Personal History Application

Document Date: _____ Number of Pages: _____

Signer(s) Other Than Named Above: _____

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U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

**Certificate No. 7303-3-2023**

## CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries , the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

**Name of Product(s)**

See Attached List

(One Page)

**Name of Manufacturer/Distributor, Address**

**Name of Manufacturer**
NEOTECH PRODUCTS, LLC
28430 Witherspoon Pkwy
Valencia, CA USA 91355

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

**This certificate is valid from April 05, 2023 to April 04, 2025.**

U.S. FOOD & DRUG ADMINISTRATION

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

**Certificate No. 7303-3-2023**

**Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1**

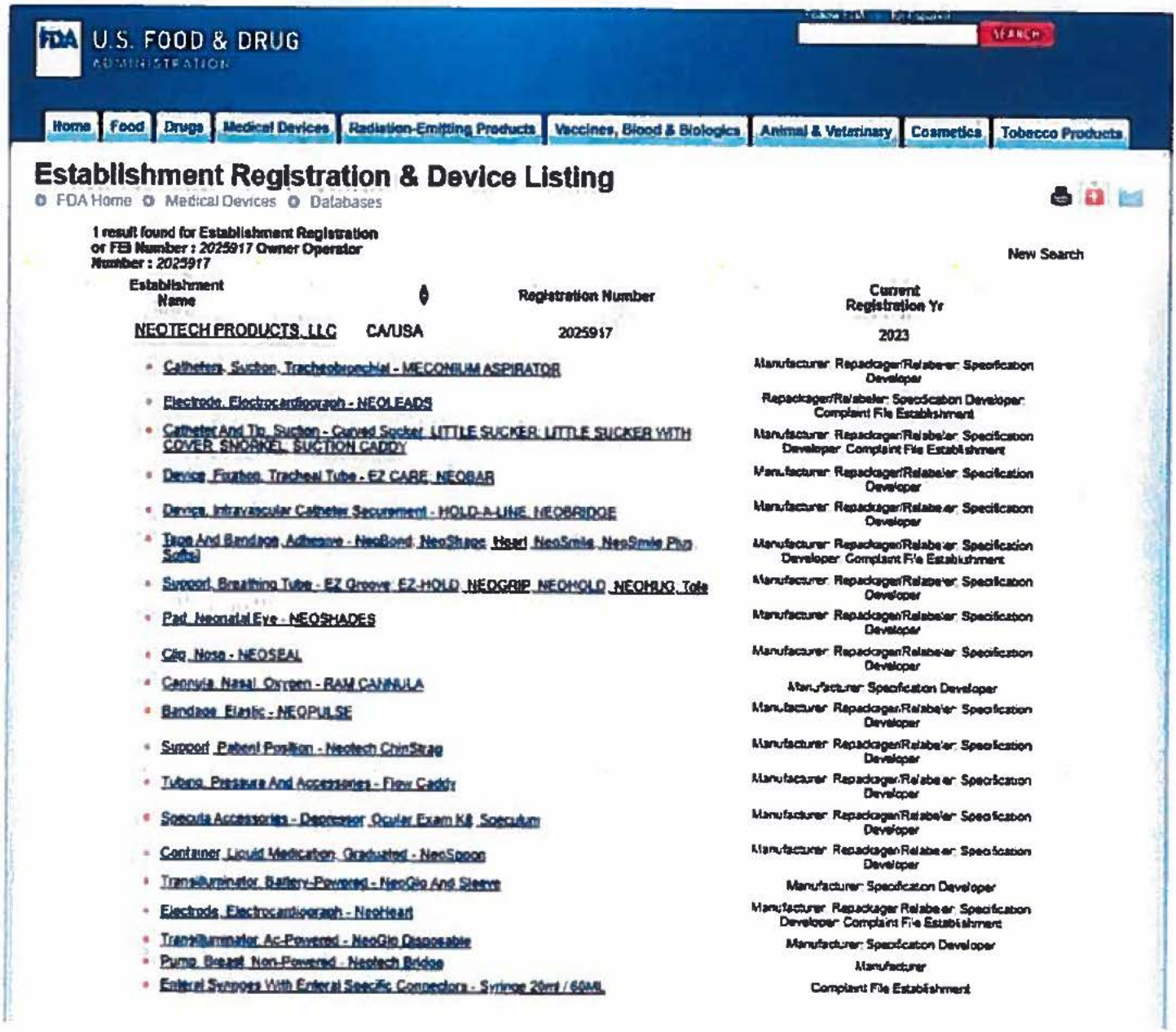
**Name of Manufacturer**

NEOTECH PRODUCTS, LLC
28430 Witherspoon Pkwy
Valencia, CA
USA 91355

**Name of Product(s)**

Neotech Bridge: N8001-5, N8001-30, N8001-KT - Non Powered Brest Pump
ChinStrap N784, N785, N786, N787, N788, N789, N790 - Support Patient Position
Curved Sucker N206, N207, N208 - Catheter and Tip Suction
EZCare N9105, N9106, N9107, N9108, N9109, N9110, N9111, N925, N926 - Device Fixation Tracheal Tube
EZ-Hold N756, N757, N758 - Support Breathing Tube
Flow Caddy N2425 - Tubing Pressure and Accessories
Hold-A-Line N705 - Device Intravascular Catheter Securement
LittleSucker N204, N204TP, N205, N205TP, N204C, N205C, N215, N224, N225, N224TP, N225TP - Catheter and Tip Suction
Meconium Aspirator N0101, N0102 - Catheters Suction Tracheobronchital
NeoBar N709, N710, N711, N712, N713, N714, N715F, N715H, N716F, N716H, N718, N719N - Tracheal Tube
NeoBond/Shape N7426, N741, N742 - Tape and Bandage Adhesive
NeoBridge N700, N701, N702 - Device Intravascular Catheter Securement
NeoGlo/Sleeves N555/N55100 & NeoGlo Disposable N5536 - LED Transilluminator
NeoGrip N601, N602, N603 - Support Breathing Tube
NeoHeart N335, N336 Electrode Electrocardiograph
NeoHug/Smile N680, N681 - Utility Device Holder
NeoLead N300, N301, N305, N306, N315 - Electrode Electrocardiograph
NeoPulse N781, N782, N783 - Bandage Elastic
NeoSeal N420, N421, N422 Clip Nose
NeoShades N720(PL)(PL-H), N721(PL)(PL-H), N722(PL)(PL-H), N724(PL), N725(PL), N726(PL), N727(PL), N728(PL), N729(PL) - Pad Neonatal Eye
NeoSmile/Plus N731, N7320 Tape and Bandage Adhesive
NeoSpoon N761 - Disposable Measuring Spoon
Ocular Exam Kit N6500, N6501, N6502, N6510, N6511, N6565 - Specula Ophthalmic Depressor Orbital Tray Surgical Instrument
RAM Cannula N4900 N4901 N4902 N4903, N4904, N4905, N4906, N4820 - Cannula Nasal Oxygen
SoftSil N745 - Silicone Adhesive Patch
Suction Caddy N245 - Catheter and Tip Suction
Telemetry Holders A501, A507 - Mobile Monitor Protection

----------END OF PRODUCT LIST----------



U.S. FOOD & DRUG ADMINISTRATION

SEARCH

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

# Establishment Registration & Device Listing

FDA Home > Medical Devices > Databases

**1 result found for Establishment Registration or FEI Number : *2025917* Owner Operator Number : *2025917***

New Search

| Establishment Name | | Registration Number | Current Registration Yr |
|---|---|---|---|
| NEOTECH PRODUCTS, LLC | CA/USA | 2025917 | 2023 |

- Catheter, Suction, Tracheobronchial - MECONIUM ASPIRATOR — Manufacturer Repackager/Relabeler Specification Developer
- Electrode, Electrocardiograph - NEOLEADS — Repackager/Relabeler Specification Developer Complaint File Establishment
- Catheter And Tip, Suction - Curved Spoker, LITTLE SUCKER, LITTLE SUCKER WITH COVER, SNORKEL, SUCTION CADDY — Manufacturer Repackager/Relabeler Specification Developer Complaint File Establishment
- Device, Fixation, Tracheal Tube - EZ CARE, NEOBAR — Manufacturer Repackager/Relabeler Specification Developer
- Device, Intravascular Catheter Securement - HOLD-A-LINE, NEOBRIDGE — Manufacturer Repackager/Relabeler Specification Developer
- Tape And Bandage, Adhesive - NeoBond, NeoShape, Heart, NeoSmile, NeoSmile Plus, Softie — Manufacturer Repackager/Relabeler Specification Developer Complaint File Establishment
- Support, Breathing Tube - EZ Groove, EZ-HOLD, NEOGRIP, NEOHOLD, NEOHUG, Tote — Manufacturer Repackager/Relabeler Specification Developer
- Pad, Neonatal Eye - NEOSHADES — Manufacturer Repackager/Relabeler Specification Developer
- Clip, Nose - NEOSEAL — Manufacturer Repackager/Relabeler Specification Developer
- Cannula, Nasal, Oxygen - RAM CANNULA — Manufacturer Specification Developer
- Bandage, Elastic - NEOPULSE — Manufacturer Repackager/Relabeler Specification Developer
- Support, Patient Position - Neotech ChinStrap — Manufacturer Repackager/Relabeler Specification Developer
- Tubing, Pressure And Accessories - Flow Caddy — Manufacturer Repackager/Relabeler Specification Developer
- Speculs Accessories - Depressor, Ocular Exam Kit, Speculum — Manufacturer Repackager/Relabeler Specification Developer
- Container, Liquid Medication, Graduated - NeoSpoon — Manufacturer Repackager/Relabeler Specification Developer
- Transilluminator, Battery-Powered - NeoGlo And Sleeve — Manufacturer Specification Developer
- Electrode, Electrocardiograph - NeoHeart — Manufacturer Repackager Relabeler Specification Developer Complaint File Establishment
- Transilluminator, Ac-Powered - NeoGlo Disposable — Manufacturer Specification Developer
- Pump, Breast, Non-Powered - Neotech Bridge — Manufacturer
- Enteral Syringes With Enteral Specific Connectors - Syringe 20ml / 60ML — Complaint File Establishment

MERCHANTS BONDING COMPANY

# POWER OF ATTORNEY

Know All Persons By These Presents, that MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., both being corporations of the State of Iowa, d/b/a Merchants National Indemnity Company (in California only) (herein collectively called the "Companies") do hereby make, constitute and appoint, individually,

**Cyndi Beilman**

their true and lawful Attorney(s)-in-Fact, to sign its name as surety(ies) and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

This Power-of-Attorney is granted and is signed and sealed by facsimile under and by authority of the following By-Laws adopted by the Board of Directors of Merchants Bonding Company (Mutual) on April 23, 2011 and amended August 14, 2015 and adopted by the Board of Directors of Merchants National Bonding, Inc., on October 16, 2015.

"The President, Secretary, Treasurer, or any Assistant Treasurer or any Assistant Secretary or any Vice President shall have power and authority to appoint Attorneys-in-Fact, and to authorize them to execute on behalf of the Company, and attach the seal of the Company thereto, bonds and undertakings, recognizances, contracts of indemnity and other writings obligatory in the nature thereof."

"The signature of any authorized officer and the seal of the Company may be affixed by facsimile or electronic transmission to any Power of Attorney or Certification thereof authorizing the execution and delivery of any bond, undertaking, recognizance, or other suretyship obligations of the Company, and such signature and seal when so used shall have the same force and effect as though manually fixed."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and authority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner-Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

In Witness Whereof, the Companies have caused this instrument to be signed and sealed this 1st day of May , 2023 .

MERCHANTS NATIONAL BONDING, INC. INCORPORATED -o- 2003

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED -o- 1933

**MERCHANTS BONDING COMPANY (MUTUAL)**
**MERCHANTS NATIONAL BONDING, INC.**
**d/b/a MERCHANTS NATIONAL INDEMNITY COMPANY**

By Larry Taylor
*President*

STATE OF IOWA
COUNTY OF DALLAS ss.

On this 1st day of May , 2023 , before me appeared Larry Taylor, to me personally known, who being by me duly sworn did say that he is President of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC.; and that the seals affixed to the foregoing instrument are the Corporate Seals of the Companies; and that the said instrument was signed and sealed in behalf of the Companies by authority of their respective Boards of Directors.

NOTARIAL SEAL IOWA
Kim Lee
Commission Number 702737
My Commission Expires
April 14, 2024

Kim Lee
*Notary Public*

(Expiration of notary's commission does not invalidate this instrument)

I, William Warner, Jr., Secretary of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., do hereby certify that the above and foregoing is a true and correct copy of the POWER-OF-ATTORNEY executed by said Companies, which is still in full force and effect and has not been amended or revoked.

In Witness Whereof, I have hereunto set my hand and affixed the seal of the Companies on this 1st day of May , 2023 .

MERCHANTS NATIONAL BONDING, INC. INCORPORATED -o- 2003

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED -o- 1933

William Warner Jr.
*Secretary*

POA 0018 (10/22)

# CALIFORNIA ALL-PURPOSE ACKNOWLEDGMENT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

STATE OF CALIFORNIA

County of San Diego }

On 05/01/2023 (Date) before me, Pam Davis (Insert Name of Notary exactly as it appears on the official seal), Notary Public,

personally appeared Cyndi Beilman (Name(s) of Signer(s))

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

Witness my hand and official seal.

PAM DAVIS
COMM. #2356823
NOTARY PUBLIC-CALIFORNIA
SAN DIEGO COUNTY
My Commission Expires
JUNE 1, 2023

Place Notary Seal Above

Signature _____ (Signature of Notary Public)

## OPTIONAL

*Though the information below is not required by law, it may prove valuable to persons relying on the document and could prevent fraudulent removal and reattachment of the form to another document.*

**Description of Attached Document**

Title or Type of Document: _____

Document Date: _____ Number of Pages: _____

Signer(s) Other Than Named Above: _____

**Capacity(ies) Claimed by Signer(s)**

Signer's Name: _____
- ☐ Individual
- ☐ Corporate Officer — Title(s): _____
- ☐ Partner ☐ Limited ☐ General
- ☐ Attorney in Fact
- ☐ Trustee
- ☐ Guardian or Conservator
- ☐ Other: _____

Signer is Representing: _____

RIGHT THUMBPRINT OF SIGNER
Top of thumb here

Signer's Name: _____
- ☐ Individual
- ☐ Corporate Officer — Title(s): _____
- ☐ Partner ☐ Limited ☐ General
- ☐ Attorney in Fact
- ☐ Trustee
- ☐ Guardian or Conservator
- ☐ Other: _____

Signer is Representing: _____

RIGHT THUMBPRINT OF SIGNER
Top of thumb here

Premium: $500.00
Premium based on final contract price is subject to audit

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

## PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 100078400

Application/License No. _____

Neotech Products LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 28430 Witherspoon Pkwy Valencia, CA 91355 (Address of Applicant/Principal), as PRINCIPAL, and Merchants Bonding Company (Mutual) (Surety Company), a corporation organized under the laws of the state of Iowa (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 6700 Westown Parkway, West Des Moines, IA 50266 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on May 1, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 1st day of May, 2023.

APPLICANT/PRINCIPAL

Neotech Products LLC

Authorized Representative

SURETY COMPANY

Merchants Bonding Company (Mutual)

Surety Company's Representative

Cyndi Beilman, Attorney-in-fact

print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

LP 4229 NV (5/21)

# 40

Y

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

**Non-Refundable $1,000 Fee**

Rev (08/17/2022)

| Where is the facility located? | ☐ Nevada ■ Out-of-State |
|---|---|

| Type of Application (check applicable box) | | Wholesaler Business Type (check applicable box) |
|---|---|---|
| ■ New Wholesaler<br>☐ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH _____ | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

### Section 1: General Information

Facility Name: OxyGo HQ Florida LLC

Physical Address: 2200 Principal Row

City: Orlando State: FL Zip: 32837

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 440 716 9962 Website: www.oxygo.life

Name of Designated Representative (DR): Victoria Marquard-Schultz

Licensing Company Email: regulatory@oxygo.life DR Email: vmarquard@oxygo.life

| Entities the Wholesaler will Serve (✓ all applicable) | Products to be Handled or Wholesaled (✓ all applicable) | Type of Wholesaling (✓ all applicable) |
|---|---|---|
| ☐ Pharmacies | ☐ Dangerous Drugs | ■ Manufacturer |
| ☐ Practitioners | ☐ Controlled Substances | ☐ Repacker |
| ☐ Hospitals | ■ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ■ Wholesalers | ☐ Others: | ☐ Warehouse |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ☐ Others: | | ☐ Others: |

| Section 2: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✔ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | ✔ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | ✔ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✔ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

5/4/2023
Date

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: Inogen Inc
Address: 301 Coromar Dr City: Goleta State: CA Zip: 93117

Name: Thunderbird Metals South
Address: PO Box 7166 City: Carol Stream State: IL Zip: 60197

Name: Ashcroft Inc.
Address: PO Box 201255 City: Dallas State: TX Zip: 75320

Name: Danyang Xinya Valve Co.
Address: No 12. DongJin Xi Road City: Yanling Town State: Jiangs Zip: China

**Section 4: Publicly Traded Corporation**

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: Florida
Parent Company (if any): Marquard Ventures Inc / Applied Marketing Services Inc
Corporation/Organization Name: OxyGo HQ Florida LLC
Mailing Address: 2200 Principal Row
City: Orlando State: FL Zip: 32837
Telephone: 440 716 9962 Email: regulatory@oxygo.life
Contact Person Name: Victoria Marquard-Schultz

**Section 6: Partnership**

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

**Section 7: Sole Owner**

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | ✔ |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | ✔ | |
| 1. Copy of FDA registration<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** | | ✓ | | |
| • **List of all partners and their percent ownership.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

OxyGo Florida HQ LLC

Facility Name

Victoria Marquard-Schultz

Print Name of Authorized Person Submitting Application



Original signature of Authorized Person (copies or stamps not accepted)

4/5/2023

Date

| Board Use Only | Date Received: 5-11-23 | Amount: 1000.00 CK-2016 |
|---|---|---|

**Sherri L. Warfel, Esquire 015181998**
**PELLETTIERI RABSTEIN & ALTMAN**
**989 Lenox Drive, Suite 101**
**Lawrenceville, NJ 08448**
**(609) 520-0900**
**swarfel@pralaw.com**
**Attorneys for Plaintiff**

| | | |
|---|---|---|
| ESTATE OF STACEY ALEXANDER, et al., | : | SUPERIOR COURT OF NEW JERSEY |
| | : | LAW DIVISION - BURLINGTON COUNTY |
| Plaintiff | : | DOCKET NO. BUR-L-2043-20 |
| | : | |
| vs. | : | Civil Action |
| | : | |
| LINCARE INC; INVACARE CORPORATION; APPLIED HOME HEALTHCARE EQUIPMENT LLC, et al., | : | **STIPULATION OF DISMISSAL WITH PREJUDICE** |
| Defendants | : | |

It is hereby stipulated and agreed that the matter in difference in the above entitled action be and is hereby dismissed with prejudice as to **DEFENDANT APPLIED HOME HEALTHCARE EQUIPMENT LLC ONLY** without costs against any party.

Sherri L. Warfel, Esquire
SHERRI L. WARFEL, ESQUIRE
Attorney for Plaintiff Alexander

DANIEL S. ALTSCHULER, ESQUIRE
Attorney for Defendant Invacare Corporation

Beth S. Rose 3/2/23
BETH S. ROSE, ESQUIRE
Attorney for Defendant Applied Home Healthcare Equipment LLC

Dated: March 1, 2023

**Sherri L. Warfel, Esquire 015181998**
**PELLETTIERI RABSTEIN & ALTMAN**
**989 Lenox Drive, Suite 101**
**Lawrenceville, NJ 08448**
**(609) 520-0900**
**swarfel@pralaw.com**
**Attorneys for Plaintiff**

| | | |
|---|---|---|
| ESTATE OF STACEY ALEXANDER, et al., | : | SUPERIOR COURT OF NEW JERSEY |
| | : | LAW DIVISION - BURLINGTON COUNTY |
| Plaintiff | : | DOCKET NO. BUR-L-2043-20 |
| | : | |
| vs. | : | Civil Action |
| | : | |
| LINCARE INC; INVACARE CORPORATION; APPLIED HOME HEALTHCARE EQUIPMENT LLC, et al., | : | **STIPULATION OF DISMISSAL WITH PREJUDICE** |
| Defendants | : | |

It is hereby stipulated and agreed that the matter in difference in the above entitled action be and hereby is dismissed with prejudice as to **DEFENDANT INVACARE CORPORATION ONLY** without costs against any party.

Sherri L. Warfel, Esquire
SHERRI L. WARFEL, ESQUIRE
Attorney for Plaintiff Alexander

DANIEL S. ALTSCHULER, ESQUIRE
Attorney for Defendant Invacare Corporation

Beth S. Rose, 3/2/23
BETH S. ROSE, ESQUIRE
Attorney for Defendant Applied Home Healthcare Equipment LLC

Dated: March 1, 2023

OxyGO Keep Going.
www.oxygo.life

July 18, 2023

RE: Application for Wholesale License

Dear Sir or Madam:

This letter is a follow up to our representative's, Steve Murphy, appearance at the Board last week. We would respectfully ask you to consider granting us a license or a temporary license for the state of Nevada.

First, upon learning we were required to have the license in Nevada, we did immediately cease and desist sale and paid the fine as well.

Second, in an effort to be abundantly clear and transparent with the Board, we disclosed the nuisance law suit that one of our subsidiaries had in the state of New Jersey. There was nothing found wrong with our products or our company and the plaintiff dismissed us from the lawsuit with prejudice and it was entered into the court as of last week.

Thank you for your consideration,

Victoria Marquard-Schultz
CEO & Co-Founder OxyGo


OxyGO
Keep Going.
www.oxygo.life

FDA

FDA Home[3] Medical Devices[4] Databases[5]

## Establishment Registration & Device Listing

New Search

Back To Search Results

**Establishment:**
OxyGo HQ Florida LLC
**Business Trade Names:**
(1) Applied Home Healthcare Equipment (2) IBEDA Inc (3) LIFE Corporation (4) SuperFlash Compressed Gas Equipment

2200 Principal Row
Orlando, FL 32837
**Registration Number:** 3008657593
**FEI Number*:** 3008657593
**Status:** Active
**Initial Distributor/Importer:** Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
**Date Of Registration Status:** 2023

**Owner/Operator:**
Applied Home Healthcare Equipment[6]
28825 Ranney Parkway
Westlake, OH US 44145
**Owner/Operator Number:** 10033565[7]

**Official Correspondent:**
Victoria Marquard-Schultz
28825 Ranney Parkway
Westlake, OH 44145
**Phone:** 440-7884099

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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Page Last Updated: 04/03/2023

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
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U.S. Department of **Health & Human Services**

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7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10033565&OwnerOperatorName=&

**OxyGo HQ Florida, LLC**
**List of Officers and Directors**

| Officer Name | Position |
|---|---|
| Victoria Marquard-Schultz | CEO |
| David Marquard II | Chairman |

**OxyGo HQ Florida, LLC**
**List of Corporation Shareholders**

| Shareholder | Ownership % |
|---|---|
| David Marquard II | 100.0% |

# *State of Florida*
## *Department of State*

I certify from the records of this office that OXYGO HQ FLORIDA LLC is a limited liability company organized under the laws of the State of Florida, filed on December 28, 2017, effective December 23, 2017.

The document number of this limited liability company is L17000263557.

I further certify that said limited liability company has paid all fees due this office through December 31, 2023, that its most recent annual report was filed on January 26, 2023, and that its status is active.

***Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twenty-ninth day of March, 2023***

***Secretary of State***

**Tracking Number: 3817774391CU**

**To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.**

**https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication**

# State of Florida
## Department of State

I certify from the records of this office that MV LIFE LLC is a limited liability company organized under the laws of the State of Florida, filed on April 19, 2021.

The document number of this limited liability company is L21000181785.

I further certify that said limited liability company has paid all fees due this office through December 31, 2023, that its most recent annual report was filed on January 26, 2023, and that its status is active.

*Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Tenth day of April, 2023*

*Secretary of State*

**Tracking Number: 5805896765CU**

**To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.**

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# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

Y

### Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler OxyGo Florida HQ LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 2200 Principal Row

City Orlando State FL Zip 32837

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 440 716 9962 Website www.oxygo.life

Licensing Company Email regulatory@oxygo.life

### Section 2: Personal Information

First David Middle J Last Marquard II

Alias(es, nicknames, name changes, etc.) Dave

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] Morey Court

City Golden Oak State FL Zip 32836

Telephone [redacted] Email dmarquard@oxygo.life

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | ✔ | |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✔ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Rocky River High School | | 1961-1965 | |
| **Address** | **City** | **State** | **Zip** |
| 20951 Detroit Road | Rocky River | OH | 44116 |
| Diploma/Degree obtained, if any | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Case Western Reserve University | | 1968-1972 | |
| **Address** | **City** | **State** | **Zip** |
| 10900 Euclid Avenue | Cleveland | OH | 44106 |
| Diploma/Degree obtained, if any | | | |
| BS | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 12/2017 -present | [redacted] Morey Court | Golden Oak | FL | 32836 |
| 09/2007-12/2017 | [redacted] Lake Road | Avon Lake | OH | 44012 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| | | | | |
|---|---|---|---|---|
| Business Name: OxyGo HQ Florida LLC | | | | From - To (MM/YY – MM/YY): 12/2014- present |
| Business Address: 2200 Principal Row | | City: Orlando | State: FL | Zip: 32837 |
| Phone: 407 533 4890 | Title: Co- Founder | | Number of Employed Hours: 6,000 + | |
| Description of Duties: management at Florida branch | | | | |

| | | | | |
|---|---|---|---|---|
| Business Name | | | | From - To (MM/YY – MM/YY) |
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| | | | | |
|---|---|---|---|---|
| Business Name | | | | From - To (MM/YY – MM/YY) |
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| | | | | |
|---|---|---|---|---|
| Business Name | | | | From - To (MM/YY – MM/YY) |
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| | | | | |
|---|---|---|---|---|
| Business Name | | | | From - To (MM/YY – MM/YY) |
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✔ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | ✔ | |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # 5 . Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| OxyGo HQ Florida LLC | | | | |

**Provide explanation below:**

There is a lawsuit pending against OxyGo in New Jersey. This matter was brought to us in the end of 2020 and has been long in discovery and is still under way, so we will give you a brief overview of the situation while maintaining confidentiality. At the end of April, the plaintiff submitted a motion to the court to dismiss us from the case with prejudice, we are just waiting for the judges stamp of approval.

Our OxyGo product is typically only put on patients that are ill with multiple co-morbidities and do not have a long term prognosis. The OxyGo is not a life sustaining product, it merely increases the quality of life of a patient. (I.e. if it were to stop working, the patient would not die, it is not a ventilator.)

The Estate of such a patient is suing because of his death. The Estate has not alleged a specific defect in our product, and is suing not only us, but also: another oxygen concentrator the patient was using, 2 different homecare providers and also left open 30 spaces for defendants they do not know exist yet (They named John Doe 1-10, John Roe 1-10 and ABC Corp 1-10 on the complaint). We have inspected the unit the patient allegedly used and found no defects. Our company has been around since 1993 and this is the first instance of a lawsuit.

Original Signature (electronic, copies or stamps not accepted)

4/10/2023
Date

I, David · J. Marquard II, **certify that as the designated representative for** OxyGo HQ LLC / LIFE Corporation,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. _____ I am at least 21 years of age;
3. _____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. _____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. _____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. _____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. _____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

David J Marquard II

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/1/2023

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

David J. Marquard II

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/4/23

Date

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**Please have this section completed in the presence of a Notary Public.**

State of Ohio, ss. County of Cuyahoga

I, Victoria Marquard, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

5/4/2023

**Date**

Subscribed and Sworn to before me this 4 day of May.

**Notary Public Signature**

Victoria Marquard-Schultz
Attorney At Law
Notary Public, State of Ohio
My commission has no expiration date
Sec. 147.03 R.C.

**(Seal)**

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/13/2022)

### Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: OxyGo Florida HQ LLC

Pharmacy/MDEG/Wholesaler License # (if applicable):

Physical Address: 2200 Principal Row

City: Orlando State: Fl Zip: 32837

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 440 716 9962 Website: www.oxygo.life

Licensing Company Email: regualtory@oxygo.life

### Section 2: Personal Information

First: David Middle: J Last: Marquard II

Alias(es, nicknames, name changes, etc.): Dave

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Morey Court

City: Golden Oak State: FL Zip: 32826

Telephone: [redacted] Email: dmarquard@oxygo.life

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | ✔ | |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✔ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Rocky River High School | | | 1961-1965 | |
| Address | | City | State | Zip |
| 20951 Detroit Road | | Rocky River | OH | 44116 |
| Diploma/Degree obtained, if any | | | | |

| School Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Case Western Reserve University | | | 1968-1972 | |
| Address | | City | State | Zip |
| 10900 Euclid Avenue | | Cleveland | OH | 44106 |
| Diploma/Degree obtained, if any | | | | |
| BS | | | | |

| School Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |

| School Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |

| School Name | | | From - To (MM/YY – MM/YY | |
|---|---|---|---|---|
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 12/2017-present | [redacted] Morey Court | Golden Oak | FL | 32836 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| 09/2007-12/2017 | [redacted] Lake Road | Avon Lake | OH | 44012 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| OxyGo HQ Florida LLC | | | 12/2014-present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 2200 Principal Row | | Orlando | OH | 32837 |
| **Phone** | **Title** | | | |
| 407 533 4890 | Co-Founder | | | |
| **Description of Duties** | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | | |
| | | | | |
| **Description of Duties** | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | | |
| | | | | |
| **Description of Duties** | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | | |
| | | | | |
| **Description of Duties** | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | | |
| | | | | |
| **Description of Duties** | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✔ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | ✔ | |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # 5 . Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

There is a lawsuit pending against OxyGo in New Jersey. This matter was brought to us in the end of 2020 and has been long in discovery and is still under way, so we will give you a brief overview of the situation while maintaining confidentiality. At the end of April, the plaintiff submitted a motion to the court to dismiss us from the case with prejudice, we are just waiting for the judges stamp of approval.

Our OxyGo product is typically only put on patients that are ill with multiple co-morbidities and do not have a long term prognosis. The OxyGo is not a life sustaining product, it merely increases the quality of life of a patient. (I.e. if it were to stop working, the patient would not die, it is not a ventilator.)

The Estate of such a patient is suing because of his death. The Estate has not alleged a specific defect in our product, and is suing not only us, but also: another oxygen concentrator the patient was using, 2 different homecare providers and also left open 30 spaces for defendants they do not know exist yet (They named John Doe 1-10, John Roe 1-10 and ABC Corp 1-10 on the complaint). We have inspected the unit the patient allegedly used and found no defects. Our company has been around since 1993 and this is the first instance of a lawsuit.

Original Signature (electronic, copies or stamps not accepted)

5/4/23
Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

David J. Marquard II

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/4/23

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Ohio, ss. County of Cuyahoga

I, Victoria Marquard, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

5/4/2023

**Date**

Subscribed and Sworn to before me this 4 day of May.

**Notary Public Signature**

**Victoria Marquard-Schultz**
Attorney At Law
Notary Public, State of Ohio
My commission has no expiration date
Sec. 147.03 R.C.

**(Seal)**

**OxyGo HQ Florida, LLC**
**List of Employees**

| Employee Name | Work State |
|---|---|
| Bishop, Michael | FL |
| Bishop, Ricky W. | FL |
| Bubna, Kevin M. | OH |
| Buchino, Louis | OH |
| Christ, James H. | OH |
| Cole, Carrie J. | OH |
| Croston, Joshua A. | OH |
| Dean, Jeremy L. | OH |
| Diaz, Arlene | FL |
| Dodge, Jayne L. | FL |
| Earls, Michael D. | OH |
| Fanara, Amanda M. | OH |
| Fichter, Brittany S. | OH |
| Flanigan, Jason R. | OH |
| Flanigan, William | OH |
| Frederick, Laura A. | OH |
| Goettel, Deja R. | AZ |
| Hogan, Kathy L. | OH |
| Hone, Jacob D. | OH |
| Ianni, Blake J. | OH |
| Keane, Katelyn E. | OH |
| Kim, Ben S. | CA |
| King, Duane L. | AZ |
| Kinley, Sandra G. | OH |
| Loewe, Adrian J. | OH |
| Marquard, Catherine | FL |
| Marquard, David | FL |
| Marquard-Schultz, Victoria E. | OH |
| Martin, Jesse | OH |
| McKay-Hughes, Tammy | OH |
| McKenzie, April S. | FL |
| Mikuls, Ken J. | MO |
| Mohr, Frank P. | OH |
| Moody, Brian K. | OH |
| Moreland, McKenzie E. | FL |
| Murphy, Steven J. | NV |
| Palmer, Elizabeth J. | OH |
| Paradis, James M. | OH |
| Roe, Jacob R. | OH |
| Schultz, Jonathan C. | OH |
| Simon, Thomas | OH |
| Sokol, Dylan M. | FL |
| Spring, Ashley A. | AZ |
| Stulock, Nicholas J. | OH |
| Tarkany, Kurt M. | OH |
| Thielman, Justin R. | OH |
| Wade, Kyle A. | FL |

**STATE OF FLORIDA**
**DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION**

FLORIDA DRUGS, DEVICES AND COSMETICS
2601 BLAIR STONE ROAD
TALLAHASSEE FL 32399-1047

(850) 487-1395

RECEIVED APR 21 2022

MV LIFE,LLC
LIFE CORPORATION
2200 PRINCIPAL ROW
ORLANDO FL 32837

Congratulations! With this license you become one of the nearly one million Floridians licensed by the Department of Business and Professional Regulation. Our professionals and businesses range from architects to yacht brokers, from boxers to barbeque restaurants, and they keep Florida's economy strong.

Every day we work to improve the way we do business in order to serve you better. For information about our services, please log onto **www.myfloridalicense.com**. There you can find more information about our divisions and the regulations that impact you, subscribe to department newsletters and learn more about the Department's initiatives.

Our mission at the Department is: License Efficiently, Regulate Fairly. We constantly strive to serve you better so that you can serve your customers. Thank you for doing business in Florida, and congratulations on your new license!

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

311300 ISSUED: 04/14/2022

MEDICAL GAS WHSL DIST
MV LIFE,LLC
LIFE CORPORATION

HAS REGISTERED under the provisions of Ch. 499 FS.
Expiration date : APR 30, 2024 L2204140000104

DETACH HERE

RON DESANTIS, GOVERNOR

MELANIE S. GRIFFIN, SECRETARY

**STATE OF FLORIDA**
**DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION**
**FLORIDA DRUGS, DEVICES AND COSMETICS**

| LICENSE NUMBER |
| --- |
| 311300 |

The MEDICAL GAS WHOLESALE DISTR
Named below HAS REGISTERED
Under the provisions of Chapter 499 FS.
Expiration date: APR 30, 2024

MV LIFE,LLC
LIFE CORPORATION
2200 PRINCIPAL ROW
ORLANDO FL 32837

ISSUED: 04/14/2022

DISPLAY AS REQUIRED BY LAW

SEQ # L2204140000104

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

### Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG OxyGo HQ Florida LLC MDEG License # (if applicable) _____

Physical Address 2200 Principal Row

City Orlando State FL Zip 32837

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 440 716 9962 Website www.oxygo.life

Licensing Company Email regulatory@oxygo.life

### Section 2: Personal Information

First David Middle J Last Marquard II

Alias(es, nicknames, name changes, etc.) Dave

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] Morey Court

City Golden Oak State FL Zip 32836

Telephone [redacted] Email dmarquard@oxygo.life

Are you a citizen of the United States? ☐ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | ✔ | |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✔ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Rocky River High School | | 1961-1965 | |
| Address | City | State | Zip |
| 20951 Detroit Road | Rocky River | OH | 44116 |
| Diploma/Degree obtained, if any | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Case Western Reserve University | | 1968-1972 | |
| Address | City | State | Zip |
| 10900 Euclid Avenue | Cleveland | OH | 44106 |
| Diploma/Degree obtained, if any | | | |
| BS | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 12/2017-present | [redacted] Morey Court | Golden Oak | FL | 32836 |
| 09/2007-12/2017 | [redacted] Lake Road | Avon Lake | OH | 44012 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| OxyGo HQ Florida LLC | | | 12/2014-present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 2200 Principal Row | | Orlando | FL | 32837 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 407 533 4890 | Co-Founder | | 1500+ | |
| **Description of Duties** | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state? | | ✔ |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline. | | ✔ |

**Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

5/4/23
Date

I, David J. Marquard II, **certify that as the MDEG Administrator for** OxyGo / LIFE Corporation, **that I (initial that you have read and meet the following requirements):**

1. ___ Have a high school diploma or its equivalent;
2. ___ Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. ___ Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. ___ Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

David J. Marquard II

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/4/23

Date

| **Board Use Only** | Date Received: 5-11-23 |
|---|---|

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# CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 01/04/2023

**THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.**

**IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).**

| PRODUCER | CONTACT NAME: Joann Justus | |
|---|---|---|
| United Agencies<br>1422 Euclid Avenue<br>Suite 510<br>Cleveland OH 44115 | PHONE (A/C, No, Ext): (216) 696-8044 | FAX (A/C, No): (216) 916-4871 |
| | E-MAIL ADDRESS: jjustus@uainc.com | |
| | INSURER(S) AFFORDING COVERAGE | NAIC # |
| | INSURER A : Westfield Insurance Company | 24112 |
| INSURED<br>Oxygo Hq Florida, LLC, Applied Marketing Services Inc., Applied Florida LLC, Applied Arizona LLC, SuperFlash Compressed Gas, Applied Home Healthcare Equipment LLC<br>28825 Ranney Parkway, Westlake OH 44145-1173 | INSURER B : | |
| | INSURER C : | |
| | INSURER D : | |
| | INSURER E : | |
| | INSURER F : | |

**COVERAGES** **CERTIFICATE NUMBER:** CL22102512232 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

| INSR LTR | TYPE OF INSURANCE | ADDL INSD | SUBR WVD | POLICY NUMBER | POLICY EFF (MM/DD/YYYY) | POLICY EXP (MM/DD/YYYY) | LIMITS | |
|---|---|---|---|---|---|---|---|---|
| A | [X] COMMERCIAL GENERAL LIABILITY<br>[ ] CLAIMS-MADE [X] OCCUR<br>GEN'L AGGREGATE LIMIT APPLIES PER:<br>[X] POLICY [ ] PRO-JECT [ ] LOC<br>[ ] OTHER: | | | TRA7248779 | 10/21/2022 | 10/21/2023 | EACH OCCURRENCE<br>DAMAGE TO RENTED PREMISES (Ea occurrence)<br>MED EXP (Any one person)<br>PERSONAL & ADV INJURY<br>GENERAL AGGREGATE<br>PRODUCTS - COMP/OP AGG | $ 1,000,000<br>$ 500,000<br>$ 5,000<br>$ 1,000,000<br>$ 2,000,000<br>$ 2,000,000 |
| A | AUTOMOBILE LIABILITY<br>[X] ANY AUTO<br>[ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS<br>[ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY | | | TRA7248779 | 10/21/2022 | 10/21/2023 | COMBINED SINGLE LIMIT (Ea accident)<br>BODILY INJURY (Per person)<br>BODILY INJURY (Per accident)<br>PROPERTY DAMAGE (Per accident) | $ 500,000<br>$<br>$<br>$ |
| A | [X] UMBRELLA LIAB [ ] OCCUR<br>EXCESS LIAB [ ] CLAIMS-MADE<br>DED RETENTION $ | | | TRA7248779 | 10/21/2022 | 10/21/2023 | EACH OCCURRENCE<br>AGGREGATE | $ 4,000,000<br>$ 4,000,000 |
| A | WORKERS COMPENSATION AND EMPLOYERS' LIABILITY<br>ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y / N [ ]<br>(Mandatory in NH)<br>If yes, describe under DESCRIPTION OF OPERATIONS below | N / A | | TRA7248779 | 10/21/2022 | 10/21/2023 | [ ] PER STATUTE [ ] OTH-ER<br>E.L. EACH ACCIDENT<br>E.L. DISEASE - EA EMPLOYEE<br>E.L. DISEASE - POLICY LIMIT | $ 1,000,000<br>$ 1,000,000<br>$ 1,000,000 |

**DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)**

**CERTIFICATE HOLDER**

For Information Purposes

**CANCELLATION**

**SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.**

**AUTHORIZED REPRESENTATIVE**

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U.S. FOOD & DRUG ADMINISTRATION

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# tablishment Registration & Device Listing

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**Establishment:**
LIFE CORPORATION
2200 Principal Row
Orlando, FL 32837
**Registration Number:** 2183615
**FEI Number*:** 2183615
**Status:** Active
**Initial Distributor/Importer:** Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
**Date Of Registration Status:** 2023

**Owner/Operator:**
Applied Home Healthcare Equipment
28825 Ranney Parkway
Westlake, OH US 44145
**Owner/Operator Number:** 10033565

**Official Correspondent:**
Victoria Marquard-Schultz
28825 Ranney Parkway
Westlake, OH 44145
**Phone:** 440-7884099

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Last Updated: 04/10/2023
If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

# NEVADA STATE BOARD OF PHARMACY

**985 Damonte Ranch Pkwy Suite 206**
**Reno, NV 89521**
**(775) 850-1440**
**Fax: (775) 850-1444**

## PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. BND 321545N

Application/License No. _____

OxyGo HQ Florida LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 2200 Principal Row Orlando, FL 32837 (Address of Applicant/Principal), as PRINCIPAL, and Westfield Insurance Company (Surety Company), a corporation organized under the laws of the state of Ohio (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Park Circle, PO Box 5001 Westfield Center, OH 44251-5001 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 17, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 1st day of May, 2023.

OxyGo HQ FL LLC

MAY 02 2023

David J. Marquard II

APPLICANT/PRINCIPAL

COMPANY

Authorized Representative

SURETY

Surety Company's Representative

Joann Justus, Attorney-in-fact

print name

WESTFIELD INSURANCE COMPANY SEAL

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

**POWER NO: 34-1265**
**Power of Attorney**

# Westfield Insurance Company

**CERTIFIED COPY**

1 Park Circle, PO Box 5001, Westfield Center, Ohio 44251-5001

*Know All Men by These Presents*, That **Westfield Insurance Company**, a corporation, hereinafter referred to individually as a "Company" duly organized and existing under the laws of the State of Ohio, and having their principal offices in Westfield Center, Medina County, Ohio, do by these presents make, constitute and appoint **Joann Justus** of **Cleveland** and State of **OH** its true and lawful Attorney(s)-in-Fact, with full power and authority hereby conferred in their name, place and stead, to execute, acknowledge and deliver

Bond Number: **BND 321545N**
Principal Name: **OxyGo HQ Florida LLC**
Obligee Name: **Nevada State Board of Pharmacy**
Bond Penalty: $ **100,000.00**

and to bind the Company thereby as fully and to the same extent as if such bond was signed by the President, sealed with the corporate seal of the applicable Company and duly attested by its Secretary, hereby ratifying and confirming all that the said Attorney(s)-in-Fact may do in the premises. Said appointment is made under and by authority of the following resolution adopted by the Board of Directors of the **Westfield Insurance Company**.

**"BE IT RESOLVED**, that the President, any Senior Executive, any Secretary or any Surety Operations Executive or other Executive shall be and is hereby vested with full power and authority to appoint any one or more suitable persons as Attorney(s)-in-Fact to represent and act for and on behalf of the Company subject to the following provisions:

The Attorney-in-Fact may be given full power and authority for and in the name of and on behalf of the Company, to execute, acknowledge and deliver, any and all bonds, recognizances, contracts, agreements of indemnity and other conditional or obligatory undertakings and any and all notices and documents cancelling or terminating the Company's liability thereunder, and any such instruments so executed by any such Attorney-in-Fact shall be as binding upon The Company as if signed by the President and sealed and attested by the Corporate Secretary."

**"BE IT FURTHER RESOLVED**, that the signature of any such designated person and the seal of the Company heretofore or hereafter affixed to any power of attorney or any certificate relating thereto by facsimile, and any power of attorney or certificate bearing facsimile signatures or facsimile seal shall be valid and binding upon the Company with respect to any bond or undertaking to which it is attached." (Each adopted at a meeting held on February 8, 2000.)

*In Witness Whereof,* **Westfield Insurance Company** has caused these presents to be signed by their **Senior Executive** and their corporate seal to be hereto affixed this **17th** day of **December 2019**.

By: **Gary W. Stumper,** *National Surety Leader and Senior Executive*

Affixed Corporate Seal

WESTFIELD INSURANCE COMPANY SEAL

State of Ohio
County of Medina ss:

CERTIFICATE

I, **Frank Carrino,** Secretary of the **Westfield Insurance Company**, do hereby certify that the above and foregoing is a true and correct copy of a Power of Attorney, executed by said Company, which is still in full force and effect; and furthermore, the resolutions of the Board of Directors, set out in the Power of Attorney are in full force and effect.

*In Witness Whereof,* I have hereunto set my hand and affixed the seal of said Company at Westfield Center, Ohio, this **1st** day of **May**, A.D. **2023**.

By: **Frank Carrino,** *Secretary*

On this **17th** day of **December**, A.D., **2019**, before me personally came **Gary W. Stumper**, to me known, who, being by me duly sworn, did depose and say, that he resides in **Hartford, CT**; that he is **National Surety Leader and Senior Executive** of **Westfield Insurance Company** the company described in and which executed the above instrument; that he knows the seal of said Company; that the seal affixed to said instrument is such corporate seal; that it was so affixed by order of the Board of Directors of said Company; and that he signed his name thereto by like order.

Notarial Seal Affixed

NOTARY PUBLIC STATE OF OHIO

By:
**David A. Kotnik,** Attorney at Law, *Notary Public*
My Commission Does Not Expire (Sec. 147.03 Ohio Revised Code)

State of Ohio
County of Medina ss.:

**BPOAC4A (combined) (12-19)**

# 4P

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

**Non-Refundable $1,000 Fee**

Rev (05/12/2022)

| **Where is the facility located?** | | ☐ Nevada ☑ Out-of-State |
|---|---|---|
| **Type of Application (check applicable box)** | | **Wholesaler Business Type (check applicable box)** |
| ☑ New Wholesaler<br>☐ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number: current MDEG license WH #: MP01095 | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: Philips Healthcare, a division of Philips North America LLC

Physical Address: 22100 Bothell Everett Hwy

City: Bothell State: WA Zip: 98021

Mailing Address (if different from physical address): Phillips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover State: MA Zip: 01810

Telephone: 425-487-7000 Website: www.usa.philips.com/healthcare

Name of Designated Representative (DR): Mark Chomiak

Licensing Company Email: beth.c.rogers@philips.com DR Email: mark.chomiak@philips.com

| **Entities the Wholesaler will Serve (✓ all applicable)** | **Products to be Handled or Wholesaled (✓ all applicable)** | **Type of Wholesaling (✓ all applicable)** |
|---|---|---|
| ☑ Pharmacies | ☐ Dangerous Drugs | ☑ Manufacturer |
| ☑ Practitioners | ☐ Controlled Substances | ☐ Repacker |
| ☑ Hospitals | ☑ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ☐ Wholesalers | ☐ Others: | ☐ Warehouse |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ☑ Others: Clinics, Nursing Home Pharmacies, and Distributors. | | ☐ Others: |

| **Section 2: History of Company** | **Yes** | **No** |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | X |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | X |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | X |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | X |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | X |

N/A

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

Date

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: N/A - No pharmaceuticals products are handled or sold. See Attachment A.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

N/A

**Section 4: Publicly Traded Corporation**

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: Delaware

Parent Company (if any): Philips Holding USA Inc.

Corporation/Organization Name: Philips Healthcare, a division of Philips North America LLC

Mailing Address: Phillips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover State: MA Zip: 01810

Telephone: 978-659-4884 Email: beth.c.rogers@philips.com

Contact Person Name: Beth C. Rogers

N/A

**Section 6: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A

**Section 7: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | X |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | X | |
| 1. Copy of FDA registration See Attachment B<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment C | | |

N/A

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** See Attachment D | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** N/A | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** See Attachment D | | ✓ | | |
| • **List of all partners and their percent ownership.** N/A | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. See Attachment E | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment F | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - Wholly-owned by parent company, Philips Holding USA Inc. | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** N/A | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) N/A | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment D | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** N/A - See Attachment G | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ See Attachment H | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). See Attachment I | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%207-1-19.pdf | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Philips Healthcare, a division of Philips North America LLC

Facility Name

Mark Chomiak

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

Aug 30th 2022

Date

| Board Use Only | Date Received: 7/3/23 | Amount: 1000-CK-911 |
|---|---|---|

## Attachment A

## Nature of Business

Philips Healthcare (Philips), a division of Philips North America LLC, is a manufacturer of prescription and non-prescription medical devices. Philips' Bothell, WA location manufactures automated external defibrillators (AEDs) to treat sudden cardiac arrest.

The Bothell location manufactures, distributes, and sells its products to domestic and international customers. All products manufactured at the Bothell location for domestic orders are shipped by Philips' Bothell, WA location. Stand-alone accessories such as replacement electrodes, batteries, and trainers may also be shipped from this location.

Provided below are the locations that manufacture and distribute:

**Manufacturing Location:**

Philips Healthcare
22100 Bothell Everett Highway
Bothell, WA 98021

**Distributing Locations:**

Philips Healthcare
22100 Bothell Everett Highway
Bothell, WA 98021

FDA

FDA Home[3] Medical Devices[4] Databases[5]

## Establishment Registration & Device Listing

New Search

Back To Search Results

**Establishment:**
Philips Ultrasound LLC
**Business Trade Names:**
(1) Philips (2) Philips Healthcare (3) Philips Medical Systems

22100 Bothell Everett Hwy
BOTHELL, WA 98021
**Registration Number:** 3019216
**FEI Number*:** 3019216
**Status:** Active
**Initial Distributor/Importer:** Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
**Date Of Registration Status:** 2023

**Owner/Operator:**

Philips Medical Systems International BV[6]
Veenpluis 6
Best, NL 5684PC
**Owner/Operator Number:** 1217116[7]

**Official Correspondent:**
Thuy Nguyen
Philips
22100 Bothell Everett Highway
Bothell, WA 98021
**Phone:** 612-4012475

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&RNum=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1217116&OwnerOperator
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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?
start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1217116&OwnerOperator

7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?
start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1217116&OwnerOperator

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing
New Search

Back To Search Results

**Establishment:**
Philips North America LLC
**Business Trade Names:**
(1) Heartstream (2) Philips (3) Philips Medical Systems

22100 Bothell Everett Hwy
Bothell, WA 98021
**Registration Number:** 3030677
**FEI Number*:** 1000524572
**Status:** Active
**Date Of Registration Status:** 2023

**Owner/Operator:**

Philips Medical Systems International BV[6]
Veenpluis 6
Best, NL 5684PC
**Owner/Operator Number:** 1217116[7]

**Official Correspondent:**
Tanya Deschmidt
Philips
22100 Bothell Everett Highway
Mailstop 292
Bothell, WA 98021
**Phone:** 425-2051272

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1217116&OwnerOperatorName=&
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1217116&OwnerOperatorName=&

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7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1217116&OwnerOperatorName=&

## Attachment D

## LLC Information

Philips Healthcare, a division of Philips North America LLC

**Philips Healthcare, a division of Philips North America LLC is wholly-owned by its parent company, Philips Holding USA Inc.**

**LLC Officers:**

**Jeff DiLullo**
*President and Chief Executive Officer*

**Joseph E. Innamorati**
*Vice President and Secretary*

**Ling Liu**
*Vice President and Treasurer*

**Paul W. Cavanaugh**
*Vice President*

**Irma I. Gomez**
*Assistant Secretary*

**Facility Manager:**

**Mark Chomiak**
*Director, Plant Leader ECR Operations*

Enclosed please find a list all site employees.

# Delaware

The First State



*I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "PHILIPS NORTH AMERICA LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-FOURTH DAY OF FEBRUARY, A.D. 2023.*

*AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "PHILIPS NORTH AMERICA LLC" WAS FORMED ON THE SIXTH DAY OF AUGUST, A.D. 1987.*

*AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.*

Jeffrey W. Bullock, Secretary of State

2134316 8300

SR# 20230692587

Authentication: 202784530

Date: 02-24-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

**Attachment G**

**Regarding the Resident State License**

Please note that the resident state licensing agency, the Washington Board of Pharmacy (Board), does not license prescription device manufacturers and distributors. Enclosed please find correspondence from the Board confirming that a license is not required.

Health

Visit our COVID-19 page for the latest updates, vaccine information, testing locations and data dashboard.



# Pharmaceutical Firms

## Pharmacy Firm Licensing

### Apply for a License

Applications and forms >

### Fee schedule

Licensing fees >

### Licensing Requirements

Controlled Substance Researcher >

Health Care Entity >

Itinerant Vendor or Peddler >

Legend Drug Sample Distributor >

Other Controlled Substance >

Pharmaceutical Wholesaler and Manufacturer v

Licensing Requirements v

- Chapter 18.64 RCW
- Chapter 246-879 WAC
- Chapter 246-889 WAC

Note: the commission will no longer license entities exclusively engaged in third-party logistics, as defined in 21 U.S.C. § 360eee(22). While the commission will not license third-party logistics providers (3PLs), 3PLs are federally required to report annually to the FDA.

A wholesaler that sell legend drugs and nonprescription, or nonprescription drugs in this state must be licensed as a wholesale distributor. A "wholesale distributor" means anyone engaged in wholesale distribution of drugs, including but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers;

warehouses; including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions. Types of practice licensed in this category:

Wholesaler Application:

- Full-line wholesaler (prescription and nonprescription drugs)
- Full-line wholesaler with controlled substances
- Over-the-Counter Drug Wholesaler
- Export Wholesaler
- Non-profit Wholesaler
- Reverse distributor
- Out-of-State Manufacturer
- Out-of-State Virtual Manufacturer
- In and Out-of-State Virtual Wholesalers
- 503B Outsourcing Facilities
- Retail pharmacies engaging in wholesale distribution

Manufacturer Applications – apply to locations in Washington state that manufacturer pharmaceuticals or engage in virtual manufacturer practice in-state only

In-state wholesalers and manufacturers are inspected before a license is issued and periodically to ensure compliance with laws and rules.

Non-resident manufacturers that sell or distribute legend drugs and nonprescription, or nonprescription drugs in this state must be licensed as a Washington pharmaceutical wholesaler and as a legend drug sample distributor if sample drugs are distributed.

No license is required for the wholesale distribution of medical devices so long as no pharmaceuticals are involved.

## State license verification

Applicants must list all states where they do or did hold credentials. This list must also include when the applicant has applied for a credential, even if a credential was not granted. The jurisdiction where the applicant is or was credentialed must complete and submit the submit the verification form (PDF). The jurisdiction must send the completed form directly to the department.

## Background questions

Applicant must answer background questions related to the owners, partners, managers, etc. If there is a positive answer to the professional liability questions the applicant must send an explanation of the nature of the case, data and summary of care given, copies of the original complaint, and the settlement or final disposition. If the case is pending, applicant must indicate status.

## Additional information/documents required

Out-of-state wholesalers must provide:

- Copy of resident state license;
- Copy of most recent inspection by the licensing authority or an explanation why it cannot be provided; and
- If applicable, a copy of the facility's federal Drug Enforcement Administration registration.

## Process for approving/denying applications

Credentialing staff members review the application and supporting documents to make an initial determination on eligibility. The recommendation is based upon the requirements outlined in Chapter 18.64 RCW, and Chapter 246-879 WAC. Credentialing supervisors approve routine applications that don't have positive answers to personal data questions, have questionable verifying documents or are otherwise "red flag" applications. "Red flag" applications are forwarded to the exception application process for determination by the appropriate disciplinary authority. An applicant will be formally notified of a denial and has the opportunity for a hearing to appeal the decision.

## Renewal requirements

Pharmaceutical wholesaler and manufacturer licenses are renewed annually on or before September 30 and may be renewed within 90 days of the expiration date.

A courtesy renewal notice will be mailed to licensee's address of record. Renewals mailed to the department must be postmarked on or before the expiration date to avoid having the license expire and accrue a late penalty.

## Location or ownership changes

A change of location to a different address requires a new application and payment of original licensing fees, including CSA.

A change in the business structure or organizational structure such as a change from sole proprietorship to a corporation or a change of more than 50 percent of ownership in a corporation requires a new application and original licensing fees, including CSA.

In-state wholesalers must pass an inspection before a new location or change of ownership license is issued.

## Third Party Logistic Providers – 3PLs

The Washington Pharmacy Quality Assurance Commission discussed third-party logistic (3PL) providers at its March 2018 business meeting. The commission decided it will no longer license entities exclusively engaged in third-party logistics, as defined in 21 U.S.C. § 360eee(22). While the commission will not license third-party logistics providers (3PLs), 3PLs are federally required to report annually to the FDA.

Poison Distributor or Poison Manufacturer ›

Precursor Drug Distributor Permit ›

Shopkeeper ›

Sodium Pentobarbital Registration Requirements ›

Washington Department of Fish and Wildlife Chemical Capture ›

ACORD®

# CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
01/03/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

| | |
|---|---|
| PRODUCER<br>Marsh USA, Inc.<br>1166 Avenue of the Americas<br>New York, NY 10036<br><br>CN101736188-GAUW-NI-22-23 | CONTACT NAME:<br>PHONE (A/C, No, Ext):<br>FAX (A/C, No):<br>E-MAIL ADDRESS: |
| INSURED<br>Philips North America LLC<br>222 Jacobs Street, 3rd Floor<br>Cambridge, MA 02141 | INSURER(S) AFFORDING COVERAGE — NAIC #<br>INSURER A : National Union Fire Insurance Co Of Pittsburgh — 19445<br>INSURER B : Safety National Casualty Corp. — 15105<br>INSURER C :<br>INSURER D :<br>INSURER E :<br>INSURER F : |

**COVERAGES** **CERTIFICATE NUMBER:** NYC-011181363-12 **REVISION NUMBER:** 10

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

| INSR LTR | TYPE OF INSURANCE | ADDL INSD | SUBR WVD | POLICY NUMBER | POLICY EFF (MM/DD/YYYY) | POLICY EXP (MM/DD/YYYY) | LIMITS | | |
|---|---|---|---|---|---|---|---|---|---|
| A | COMMERCIAL GENERAL LIABILITY<br>CLAIMS-MADE [X] OCCUR<br>GEN'L AGGREGATE LIMIT APPLIES PER:<br>[X] POLICY [ ] PRO-JECT [ ] LOC<br>OTHER: | | | 536-18-48 | 12/31/2022 | 12/31/2023 | EACH OCCURRENCE<br>DAMAGE TO RENTED PREMISES (Ea occurrence)<br>MED EXP (Any one person)<br>PERSONAL & ADV INJURY<br>GENERAL AGGREGATE<br>PRODUCTS - COMP/OP AGG | $<br>$<br>$<br>$<br>$<br>$ | 2,000,000<br>500,000<br>10,000<br>2,000,000<br>5,000,000<br>5,000,000 |
| B | AUTOMOBILE LIABILITY<br>[X] ANY AUTO<br>OWNED AUTOS ONLY<br>HIRED AUTOS ONLY<br>SCHEDULED AUTOS<br>NON-OWNED AUTOS ONLY | | | CA6675481 | 12/31/2022 | 12/31/2023 | COMBINED SINGLE LIMIT (Ea accident)<br>BODILY INJURY (Per person)<br>BODILY INJURY (Per accident)<br>PROPERTY DAMAGE (Per accident) | $<br>$<br>$<br>$ | 2,000,000 |
| A | [X] UMBRELLA LIAB [X] OCCUR<br>EXCESS LIAB CLAIMS-MADE<br>DED RETENTION $ | | | 10-736-193 | 12/31/2022 | 12/31/2023 | EACH OCCURRENCE<br>AGGREGATE | $<br>$ | 5,000,000<br>5,000,000 |
| B<br>B | WORKERS COMPENSATION AND EMPLOYERS' LIABILITY<br>ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [N] N/A<br>(Mandatory in NH)<br>If yes, describe under DESCRIPTION OF OPERATIONS below | | | LDS4047559 (AOS)<br>PS4047560 (WI) | 12/31/2022<br>12/31/2022 | 12/31/2023<br>12/31/2023 | [X] PER STATUTE [ ] OTH-ER<br>E.L. EACH ACCIDENT<br>E.L. DISEASE - EA EMPLOYEE<br>E.L. DISEASE - POLICY LIMIT | $<br>$<br>$ | 2,000,000<br>2,000,000<br>2,000,000 |
| A | CYBER LIABILITY | | | 03-932-59-76<br>'Subject to a policy deductible' | 12/31/2022 | 12/31/2023 | Occurrence Limit<br>Aggregate Limit | | 10,000,000<br>10,000,000 |

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Additional Certificate Holder: Virginia Community College System Commonwealth of Virginia Virginia Community College System 147 Daleville Centre Drive Daleville, VA 24083.

Evidence of coverage.

**CERTIFICATE HOLDER**

Philips North America LLC
See above for the Complete Cert. Holder Name
222 Jacobs Street, 3rd Floor
Cambridge, MA 02141

**CANCELLATION**

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Marsh USA Inc.

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AGENCY CUSTOMER ID: CN101736188
LOC #: New York

# ADDITIONAL REMARKS SCHEDULE



| AGENCY | NAMED INSURED |
|---|---|
| Marsh USA, Inc. | Philips North America LLC<br>222 Jacobs Street, 3rd Floor<br>Cambridge, MA 02141 |
| POLICY NUMBER | |
| CARRIER / NAIC CODE | EFFECTIVE DATE: |

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Named Insured Includes:
370 West Trimble Road LLC
AllParts Medical, LLC
BioTelemetry, Inc.
BioTel Research, LLC
BioTelemetry Care Management, LLC
Telcare Medical Supply, LLC
Telcare, LLC
Braemar Manufacturing, LLC
Cardiac Monitoring Holding Company, LLC
LifeWatch Corp.
LifeWatch Services, Inc.
Cardiologs Technologies Inc.
CardioNet, LLC
BioTel INR, LLC
Geneva Healthcare, LLC
VirtualScopics, LLC
Blue Willow Systems LLC
Discus Holdings, LLC
Discus Dental, LLC
Discus International, LLC
Discus Dental Canada, LLC
Electrical Geodesics LLC
Cerebral Data Systems, Inc. (CDS)
Intact Vascular, Inc.
Philips CS Corporation (formerly "Vita Topco, Inc." and "Philips Capsule Corporation")
Capsule Technologies, Inc.
CapsuleTech, Inc.
Philips Healthcare Informatics, Inc.
Philips Image Guided Therapy Corporation
Cardioprolific Inc.
Crux Biomedical, LLC
Spectranetics LLC
Volcano Atheromed, Inc.
Philips Medical Systems (Cleveland), Inc.
Philips Medical Systems MR, Inc.
Philips DS North America LLC
Philips North America, LLC
Philips North America, LLC D/B/A Philips Healthcare
Philips Oral Healthcare, LLC
Philips RS North America Holding Corporation
Philips RS North America LLC
Respironics California, LLC
Respironics Colorado, Inc.
Respironics Logistics Services, LLC
Respironics Novametrix, LLC
Philips Semiconductors Inc.
Remote Diagnostics Technologies LLC


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AGENCY CUSTOMER ID: CN101736188
LOC #: New York

# ADDITIONAL REMARKS SCHEDULE



| AGENCY | NAMED INSURED |
|---|---|
| Marsh USA, Inc. | Philips North America LLC<br>222 Jacobs Street, 3rd Floor<br>Cambridge, MA 02141 |
| POLICY NUMBER | |
| CARRIER / NAIC CODE | EFFECTIVE DATE: |

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Respiratory Technologies, Inc.
Tomtec Corporation
TR Management Company, LLC
U.S. Philips Corporation
Vesper Medical, Inc.
VISICU, Inc.
VitalHealth Software Corp.
Wellcentive LLC (formerly "Wellcentive, Inc.")
Wellcentive QR, LLC
American Color & Chemical, L.L.C.
ATL Ultrasound, Inc.
Philips Ultrasound LLC (formerly "Philips Ultrasound, Inc.")
ATL International LLC
Philips Electronics North America Foundation
Philips Electronics Realty, LLC
Philips Medical Systems Export, Inc.
Philips MPEG Inc.
Philips Project Management, LLC


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# Western Surety Company

## POWER OF ATTORNEY APPOINTING INDIVIDUAL ATTORNEY-IN-FACT

**Know All Men By These Presents,** That WESTERN SURETY COMPANY, a South Dakota corporation, is a duly organized and existing corporation having its principal office in the City of Sioux Falls, and State of South Dakota, and that it does by virtue of the signature and seal herein affixed hereby make, constitute and appoint Kristin S. Bender

, Individually

of Morristown, New Jersey, its true and lawful Attorney(s)-in-Fact with full power and authority hereby conferred to sign, seal and execute for and on its behalf bonds, undertakings and other obligatory instruments of similar nature

**- In Unlimited Amounts -**

Surety Bond Number: 30185503
Principal: See attached list of principals
Obligee: State of Nevada and Nevada State Board of Pharmacy

and to bind it thereby as fully and to the same extent as if such instruments were signed by a duly authorized officer of the corporation and all the acts of said Attorney, pursuant to the authority hereby given, are hereby ratified and confirmed.

This Power of Attorney is made and executed pursuant to and by authority of the By-Law printed on the reverse hereof, duly adopted, as indicated, by the shareholders of the corporation.

**In Witness Whereof,** WESTERN SURETY COMPANY has caused these presents to be signed by its Vice President and its corporate seal to be hereto affixed on this 2nd day of February, 2021.

WESTERN SURETY COMPANY

Paul T. Bruflat

Paul T. Bruflat, Vice President

State of South Dakota }
County of Minnehaha } ss

On this 2nd day of February, 2021, before me personally came Paul T. Bruflat, to me known, who, being by me duly sworn, did depose and say: that he resides in the City of Sioux Falls, State of South Dakota; that he is the Vice President of WESTERN SURETY COMPANY described in and which executed the above instrument; that he knows the seal of said corporation; that the seal affixed to the said instrument is such corporate seal; that it was so affixed pursuant to authority given by the Board of Directors of said corporation and that he signed his name thereto pursuant to like authority, and acknowledges same to be the act and deed of said corporation.

My commission expires
March 2, 2026

M. BENT
NOTARY PUBLIC
SOUTH DAKOTA

M. Bent

M. Bent, Notary Public

**CERTIFICATE**

I, L. Nelson, Assistant Secretary of WESTERN SURETY COMPANY do hereby certify that the Power of Attorney hereinabove set forth is still in force, and further certify that the By-Law of the corporation printed on the reverse hereof is still in force. In testimony whereof I have hereunto subscribed my name and affixed the seal of the said corporation this 21 day of April, 2023.

WESTERN SURETY COMPANY

L. Nelson

L. Nelson, Assistant Secretary

Form F4280-2-2021

**Authorizing By-Law**

## ADOPTED BY THE SHAREHOLDERS OF WESTERN SURETY COMPANY

This Power of Attorney is made and executed pursuant to and by authority of the following By-Law duly adopted by the shareholders of the Company.

Section 7. All bonds, policies, undertakings, Powers of Attorney, or other obligations of the corporation shall be executed in the corporate name of the Company by the President, Secretary, and Assistant Secretary, Treasurer, or any Vice President, or by such other officers as the Board of Directors may authorize. The President, any Vice President, Secretary, any Assistant Secretary, or the Treasurer may appoint Attorneys in Fact or agents who shall have authority to issue bonds, policies, or undertakings in the name of the Company. The corporate seal is not necessary for the validity of any bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation. The signature of any such officer and the corporate seal may be printed by facsimile.

# WESTERN SURETY COMPANY
## Sioux Falls, South Dakota
## Statement of Net Admitted Assets and Liabilities
## December 31, 2021

### ASSETS

| | | |
|---|---|---|
| Bonds | $ | 1,940,298,870 |
| Stocks | | 19,721,943 |
| Cash, cash equivalents, and short-term investments | | 32,146,891 |
| Receivables for securities | | 140,000 |
| Investment income due and accrued | | 17,433,547 |
| Premiums and considerations | | 54,366,110 |
| Amounts recoverable from reinsurers | | 3,204,634 |
| Current federal and foreign income tax recoverable and interest thereon | | - |
| Net deferred tax asset | | 14,565,007 |
| Receivable from parent, subsidiaries, and affiliates | | 14,891,869 |
| Other assets | | 1,037 |
| Total Assets | $ | 2,096,769,908 |

### LIABILITIES AND SURPLUS

| | | |
|---|---|---|
| Losses | $ | 214,859,103 |
| Loss adjustment expense | | 48,667,258 |
| Commissions payable, contingent commissions and other similar charges | | 10,885,216 |
| Other expenses (excluding taxes, license and fees | | - |
| Taxes, License and fees (excluding federal and foreign income taxes) | | 2,781,662 |
| Federal and foreign income taxes payable | | 300,285 |
| Unearned premiums | | 263,317,295 |
| Advance premiums | | 6,618,279 |
| Ceded reinsurance premiums payable (net of ceding commissions) | | 5,081,348 |
| Amounts withheld or retained by company for account of other | | 10,237,011 |
| Provision for reinsurance | | 6,261,560 |
| Payable to parent, subsidiaries and affiliates | | 7,170 |
| Payable on security transactions | | 35,226 |
| Other liabilities | | 155,189 |
| Total Liabilities | $ | 569,206,602 |

| | | | |
|---|---|---|---|
| Surplus Account: | | | |
| Common stock | $ 4,000,000 | | |
| Gross paid in and contributed surplus | 286,896,195 | | |
| Unassigned funds | 1,236,667,111 | | |
| Surplus as regards policyholders | | $ | 1,527,563,306 |
| Total Liabilities and Capital | | $ | 2,096,769,908 |

I, Julie Lee, Assistant Vice President of Western Surety Company hereby certify that the above is an accurate representation of the financial statement of the Company dated December 31, 2021, as filed with the various Insurance Departments and is a true and correct statement of the condition of Western Surety Company as of that date.

WESTERN SURETY COMPANY

By Julie Lee
Assistant Vice President, External Reporting

Subscribed and sworn to me this 14th day of March, 2022.

My commission expires:

"OFFICIAL SEAL"
CHRISTOPHER LOPATOWSKI
Notary Public, State of Illinois
My Commission Expires 01/14/2024

By Christopher Lopatowski
Notary Public

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

## PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 30185503

Application/License No. _____

*See attached list of principal names (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is *See attached list of principal addresses (Address of Applicant/Principal), as PRINCIPAL, and Western Surety Company (Surety Company), a corporation organized under the laws of the state of South Dakota (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 151 N Franklin Street Chicago, IL 60606 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 21, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 21st day of April, 20 23.

APPLICANT/PRINCIPAL

**See attached principal signature page

Authorized Representative

SIGNED and SEALED in the presence of:

Witness

Witness

SURETY COMPANY

Western Surety Company

Surety Company's Representative

Kristin S. Bender, Attorney-in-fact

print name

Nevada Non-Resident Producer License No. 829075

SIGNED and SEALED in the presence of:

Witness Jessica Iannotta

Witness April D. Peréz

Countersigned by:

N/A

Nevada Resident Agent

**APPLICANT/PRINCIPALS:**

AllParts Medical, LLC, 400 Brick Church Park Drive, Nashville, TN 37207
Discus Dental, LLC, 1700 A South Baker Ave., Ontario, CA 91761
Philips Healthcare Informatics, Inc., 4430 Rosewood Drive, Suite 200, Pleasanton, CA 94588
Philips Healthcare, a division of Philips North America LLC, 22100 Bothell Everett Hwy, Bothell, WA 98021
Philips Healthcare, a division of Philips North America LLC, 222 Jacobs Street, Cambridge, MA 02141 Philips Ultrasound LLC, 22100 Bothell Everett Highway, Bothell, WA 98021
Philips Image Guided Therapy Corporation, 3721 Valley Center Drive, Suite 500, San Diego, CA 92130
Philips Image Guided Therapy Corporation, 2451 Mercantile Drive, Rancho Cordova, CA 95742
Respironics Logistics Services, LLC, 174 Tech Center Drive, Suite 200, Mt. Pleasant, PA 15666
Spectranetics LLC, 9965 Federal Drive, Colorado Springs, CO 80921
Visicu, Inc., 217 E. Redwood Street, Suite 1900, Baltimore, MD 21202

Authorized Representative - Paul Cavanaugh

Witness

Witness

Philips RS North America LLC, 1010 Murry Ridge Lane, Murrysville, PA 15668
Philips RS North America LLC, 174 Tech Center Drive, Suite 100, Mt. Pleasant, PA 15666

Authorized Representative - Stuart Cashman

Witness

Witness

Philips RS North America LLC LIMITED LIABILITY COMPANY SEAL 1984 DELAWARE

DISCUS DENTAL LLC LIMITED LIABILITY SEAL 2007 CALIFORNIA COMPANY

PHILIPS NORTH AMERICA LLC LIMITED LIABILITY SEAL 1987 DELAWARE COMPANY

PHILIPS ULTRASOUND LLC LIMITED LIABILITY SEAL 1973 WASHINGTON COMPANY

SPECTRANETICS LLC LIMITED LIABILITY SEAL 1988 DELAWARE COMPANY

PHILIPS IMAGE GUIDED THE SEAL 2000

## Attachment H

## Medical Devices, Equipment and Gases (MDEG) Administrator Form

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of MDEG: Philips Healthcare, a division of Philips North America LLC — MDEG License # (if applicable): MP01095

Physical Address: 22100 Bothell Everett Highway

City: Bothell — State: WA — Zip: 98021

Mailing Address (if different from physical address): Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover — State: MA — Zip: 01810

Telephone: 425-487-7000 — Website: www.usa.philips.com/healthcare

Licensing Company Email: beth.c.rogers@philips.com

**Section 2: Personal Information**

First: Mark — Middle: N/A — Last: Chomiak

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☑ M ☐ F ☐ X

Mailing Address: Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover — State: MA — Zip: 01810

Telephone: [redacted] — Email: mark.chomiak@philips.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| University of Washington | | 09/~~77~~ ~~01~~ 06/01 | |
| Address | ~~City~~ | ~~State~~ | ~~Zip~~ |
| Bailrigg, Lancaster LA1 4YW, United Kingdom | | | |
| Diploma/Degree obtained, if any | | | |
| M.S., Engineering Project Management | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Metropolitan University of Leeds | | 09/~~85~~ ~~89~~ 05/89 | |
| Address | ~~City~~ | ~~State~~ | ~~Zip~~ |
| Leeds LS1 3HE, United Kingdom | | | |
| Diploma/Degree obtained, if any | | | |
| B.Eng. (Hons), Manufacturing Systems Engineering | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| COUNTHILL COMPREHENSIVE. | | 09/75 - 07/70 | |
| Address | City | State | Zip |
| | OLDHAM | LANCS | UK. |
| Diploma/Degree obtained, if any | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 05/15 – TODATE | [redacted] 113th Pl W | Edmonds / Woodway | WA | 98020 |
| 06/11 – TODATE | [redacted] PUCKERBRUSH WAY | MARION | MA | 02738 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Philips Healthcare, a division of Philips North America LLC | | | 05/19 - Present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 22100 Bothell Everett Highway | | Bothell | WA | 98021 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 425-487-7000 | Director, Plant Leader ECR Operations | | 40 hours per week | |
| **Description of Duties** | | | | |
| Manages an integral production unit of Manufacturing to deliver products against lowest cost, according to planning and quality requirements. Defines the mid-term manufacturing policy within the constraints of the business strategy. | | | | |

N/A

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

Continue on next page if additional space is needed.

N/A

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state? | | ✔ |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline. | | ✔ |

N/A

**Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| | | | | |
| Reason/Charge | | | | |
| | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| | | | | |
| Name of Business/Industry/Entity | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

Aug 20th 2022
Date

I, Mark Chomiak, **certify that as the MDEG Administrator for**

Philips Healthcare, a division of Philips North America LLC,

**that I (initial that you have read and meet the following requirements):**

1. MC Have a high school diploma or its equivalent;
2. MC Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MC Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MC Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Mark Chomiak
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Aug 30th 2022
Date

| Board Use Only | Date Received: 7.3.23 |
|---|---|

**Attachment F**

**Designated Representative Form**

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

### Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Philips Healthcare, a division of Philips North America LLC

Pharmacy/Wholesaler License # (if applicable): Pending; current MDEG license #: MP01095

Physical Address: 22100 Bothell Everett Highway

City: Bothell State: WA Zip: 98021

Mailing Address (if different from physical address): Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover State: MA Zip: 01810

Telephone: 425-487-7000 Website: www.usa.philips.com/healthcare

Licensing Company Email: beth.c.rogers@philips.com

### Section 2: Personal Information

First: Mark Middle: N/A Last: Chomiak

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover State: MA Zip: 01810

Telephone: [redacted] Email: mark.chomiak@philips.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) |
|---|---|---|
| University of Lancaster | | 09/99 06/01 (09/99 – 06/01) |
| Address | ~~City~~ / ~~State~~ / ~~Zip~~ | |
| Bailrigg, Lancaster LA1 4YW, United Kingdom | | |
| Diploma/Degree obtained, if any | | |
| M.S., Engineering Project Management | | |

| School Name | | From - To (MM/YY – MM/YY) |
|---|---|---|
| Metropolitan University of Leeds | | 09/85-05/89 (09/85 – 05/89) |
| Address | ~~City~~ / ~~State~~ / ~~Zip~~ | |
| Leeds LS1 3HE, United Kingdom | | |
| Diploma/Degree obtained, if any | | |
| B.Eng. (Hons), Manufacturing Systems Engineering | | |

| School Name | | From - To (MM/YY – MM/YY) |
|---|---|---|
| Counthill Comprehensive | | 09/75 – 07/80 |
| Address | City: OLDHAM | State: UK / Zip |
| Diploma/Degree obtained, if any | | Lancs, United Kingdom |

| School Name | | From - To (MM/YY – MM/YY) |
|---|---|---|
| | | |
| Address | City | State / Zip |
| | | |
| Diploma/Degree obtained, if any | | |
| | | |

| School Name | | From - To (MM/YY – MM/YY |
|---|---|---|
| | | |
| Address | City | State / Zip |
| | | |
| Diploma/Degree obtained, if any | | |
| | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 05/15 - To Date | [redacted] 113th Pl W | Edmonds / Woodway | WA | 98020 |
| 06/11 - To Date | [redacted] Puckerbrush Way | MARION | MA | 02738 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Philips Healthcare, a division of Philips North America LLC | | | 05/19 - Present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 22100 Bothell Everett Highway | | Bothell | WA | 98021 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 425-487-7000 | Director, Plant Leader ECR Operations | | 40 hours per week | |
| **Description of Duties** | | | | |
| Manages an integral production unit of Manufacturing to deliver products against lowest cost, according to planning and quality requirements. Defines the mid-term manufacturing policy within the constraints of the business strategy. | | | | |

N/A

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

Continue on next page if additional space is needed.

N/A

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

N/A

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

Aug 30th 2022
Date

I, Mark Chomiak, **certify that as the designated representative for**

Philips Healthcare, a division of Philips North America LLC,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. MC I am at least 21 years of age;
3. MC I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MC I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MC I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MC I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MC I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Mark Chomiak

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Aug 30th 2022

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Mark Chomiak
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Aug 30th 2022
Date

---

**Please have this section completed in the presence of a Notary Public.**

State of WASHINGTON, ss. County of KING.

I, MARK CHOMIAK, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

Aug 30th 2022
**Date**

Subscribed and Sworn to before me this 30 day of August 2022

**Notary Public Signature**

CHRISTINE NDAYIZIGA
Notary Public
State of Washington
Commission # 83209
My Comm. Expires Jun 10, 2023

**(Seal)**

## Employee List

Aaron Robbins
Aaron Smith
Abdul Nyange
Abdul Rahim
Adam Dubrow
Adam Sailer
Airaj Ahmed
Alex Crocco
Whitney Horton
Alfredo Zan
Aly Brown
Allen Stapleton
Allison Chin Burgin
Anders Sjavik
Andreas Pope
Andy Duong
Angelica Leuth
Angie Ekse
Ann Rowe
Pia Bueno
Anthony Sawicki
Antonio Menendez
Arvind Narang
Atle Larsen
Aubra Colby
Bahara Shefa
Barbara Sage
Beth Sutherland
Bettina Thompson
Boris Pavlov
Brandon Sofie
Breeana Olsen
Brett Sodini
Brian Arbanas
Brian Christopherson
Brian Kotila
Briseida Cruz
Bruce Grewell
Bruce Qualey
Carlo Macalinao
Casey Engstrom
Chantha Pich
Chanthou Lem
Charles Hills
Charles Moses
Charles Shipman
Cheng Hak
Chenguang Liu
Christina Duarte-Mendoza
Christy Goodwin
Christina Sears
Christine Gahn
Christine Ndayiziga
Christopher Henkel
Christopher Mcnicoll
Cj Murray
Cintia De Barros
Colleen Nickolette
Dale Chermak
Damian Ashby
Dan Coder
Dana Tackett
Daniel Cruz
Daniel Huang
Daniel Kim
Daniel Lee
Daniel Noose
Darek Bielawski
David Lovejoy
Dawn Jorgenson
Debbie Walty
Debbie Sullivan
Declon Gannon
Deepa Mohanasundaram
Delaney Burns
Dexter Phanekham
Donald Baker
David Kim
Douglas Powell
Dustin Frame
Edward Hann
Edward Kompare
Edward Stinson
Katy Ivanova
Elizabeth Lozano
Ellen Miller
Erica Johnson
Etesh Dua
Ethan Fabela
Etik Lianawati
Evelyn Babajany
Felicia Tishkevich
Gaudencio Sotelo
Gaurav Kapoor
Geoff Crow
George Yao
Grant Bishop
Greg Lancaster
Gregory Brink
Grace Chen
Guncha Mandal
Gwen St. Pierre
Hagger Habtemariam
Haiyun Ying
Hallie McGahuey
Hamoon Daghigh
Harini Gopal
Harpreet Kaur
Hiroko Austin
Holly Hudson
Hong Bui
Hunter Fitzgerald
Huorng Young
Jake Zeimantz

Jacqueline Nishino
Jagadeesh Kandagatla
James Watts
Jamie La Boda
Janine Hanson
Jarom Shewell
Jeff Hunt
Jennifer Huffman
Jennifer O'Brien
Jess Foster
Jesus Lerma-lizarraga
Jill LeDoux
Jinho Hur
Joel Vargas
John Buchholz
John Larkins
John Tobey
Jon Olsen
Jonathan Thaopaset
Jon Van Wechel
Jose Godoy
Joseph Diederichs
Wayne Kirkendall
Joe Mann
Joe Thompson
Joshua Cole
Julie Ross
Justin Grimley
Kai Zhang
Karl Frosh
Karn Kunal
Karolyn Kometz
Kathleen Armstrong
Keefe Mcclung
Keith Krist
Kenneth Florczak
Kevin Burgett
Kevin Talbot
Kim Nguyen
Kimberly Bui
Kimberly Sheehy
Krassimir Angelov
Krystle Tibule
Kurt Williams
Kwong Shek
Kyle Koelsch
Kyle Tibule
Laaina Fakahua
Laila Mattei
Leanne Hartman
Laurel Purcell
Leigh Perry White
Len Maio
Leta Carson
Lezley Smith
Liezel Boyance
Linda Foster
Lisa Dammeyer
Lisa Miller
Lisa Gable
Lokesh Jonnalagadda
Lorne Roy
Luat Nguyen
Lucero Garcia
Lukasz Kutek
Luyen Nguyen
Maija Tuomi
Maria Niton
Maria Villena
Mariekarmen Rueda
Mark Brown
Mark Chomiak
Mark Fiebig
Martin Caspe
Mary Frances Feider
Mary Redman
Matt Johnson
Matt Morse
Matthew Soappman
Maya Gulland
Melissa Basnight
Melissa Olejniczak
Melody Tibule
Melvin Dagunan
Melyssa Aguilera
Mengqi Gao
Michael Diep
Michael Lockhart
Mike Owens
Michael Parks
Michael Shiery
Michaela Williams
Michelle Johnson
Monica Cornejo
Monika Sudhakar Pawar
Nancy Moreyra
Nathalie Ellrodt
Nathan Thunder
Neelam Singh
Neha Hardiya
Nenita Beck
Nicholas Moon
Nick Reimer
Nishant Nair
Niya Gu
Noor Ahmed
Panhini Swaroop Sagabala
Trish Stackpole
Patrick Hauge
Paul Geary
Paul Naumann
Pete Fraser
Phan Siharath
Pia Abarca
Pinkybel Jose
Kara Humphrey
Polly Hutchison
Princess Umbao
Rachel Espiritu
Rachna Sharma
Rajat Bhiwani
Ram Rajesh Reddy Karnati
Ravi Naik

Richa Rajwar
Dick Sisalak
Rithy Mang
Robert Monahan
Roland Schnippering
Ron Cox
Rosalee Celis
Ryan Landon
Samantha Meyer
Santos Gonzalez
Saranraj Annamalai
Satomi Honda
Saurya Sinha
Schuyler Schepman
Scott Wallace
Sean Weathers
Shailendra Siddharth
Shannon Elam
Shannon O'Malley
Shawn Rose
Shawna Carp
Shayna Larson
Shirin Hajeb
Shiv Gopalkrishnan
Shujie Chen
Sini Sreenivas
Sital Shrestha
Sok Tan
Soprathna Hin
Sothy Em
Stacey Brattain
Stacy Gehman
Stephanie Carstens
Stephanie Luna-Villasana
Stephen Mckinley
Steven Duce
Steve Hugh
Steven Sierra
Subramanya Inuguri
Sumanth Kakarla
Nick Ryu
Taelyn Utter
Teri Colbert
Thomas Kimble
Thongdam Sei
Thongsay Ayasith
Thusitha Mabotuwana
Thuy Hoang
Travis Abel
Travis Rager
Vanessa Curiel
Venumadhav Vavilala
Veronique Biashikila
Vikram Mysore Ananthakrishna
Vincence Talert
Violet Cole
Vitaliy Verbitskiy
Willma Lau
Walter Hermanowski
Whitney Rabinowitz
William Jonsson
Xiao Jun Zheng （郑晓军）
Yad Khatra
Yael Tropen

# 4Q

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

**Non-Refundable $1,000 Fee**

Rev (05/12/2022)

| Where is the facility located? | | ☐ Nevada ☑ Out-of-State |
|---|---|---|
| **Type of Application (check applicable box)** | | **Wholesaler Business Type (check applicable box)** |
| ☑ New Wholesaler<br>☐ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number: current MDEG license WH #: MP01126 | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: Philips Healthcare, a division of Philips North America LLC

Physical Address: 222 Jacobs Street

City: Cambridge State: MA Zip: 02141

Mailing Address (if different from physical address): Phillips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover State: MA Zip: 01810

Telephone: 617-245-5900 Website: www.usa.philips.com/healthcare

Name of Designated Representative (DR): Jeffrey S. DeSanty

Licensing Company Email: beth.c.rogers@philips.com DR Email: jeff.desanty@philips.com

| Entities the Wholesaler will Serve (✓ all applicable) | Products to be Handled or Wholesaled (✓ all applicable) | Type of Wholesaling (✓ all applicable) |
|---|---|---|
| ☑ Pharmacies | ☐ Dangerous Drugs | ☑ Manufacturer |
| ☑ Practitioners | ☐ Controlled Substances | ☐ Repacker |
| ☑ Hospitals | ☑ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ☑ Wholesalers | ☐ Others: | ☐ Warehouse |
| ☑ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ☑ Others: Clinics and Distributors. | | ☐ Others: |

| Section 2: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | X |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | X |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | X |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | X |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | X |

N/A

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| | | | | |
| Reason/Charge | | | | |
| | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| | | | | |
| Name of Business/Industry/Entity | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

Date

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: N/A - No pharmaceuticals products are handled or sold. See Attachment A.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

N/A

**Section 4: Publicly Traded Corporation**

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: Delaware

Parent Company (if any): Philips Holding USA Inc.

Corporation/Organization Name: Philips Healthcare, a division of Philips North America LLC

Mailing Address: Phillips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover State: MA Zip: 01810

Telephone: 978-659-4884 Email: beth.c.rogers@philips.com

Contact Person Name: Beth C. Rogers

N/A

**Section 6: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A

**Section 7: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | X |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | N/A |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | X | |
| 1. Copy of FDA registration See Attachment B<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment C | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** See Attachment D | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** N/A | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** See Attachment D | | ✓ | | |
| • **List of all partners and their percent ownership.** N/A | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. See Attachment E | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment F | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - Wholly-owned by parent company, Philips Holding USA Inc. | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** N/A | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) N/A | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment D | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** N/A - See Attachment G | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ See Attachment H | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). See Attachment I | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | N/A |
| • **Submit Fingerprints** following instructions found at: https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%207-1-19.pdf | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Philips Healthcare, a division of Philips North America LLC
Facility Name

Jeffrey S. DeSanty
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

12/7/2022
Date

| Board Use Only | Date Received: 7/3/23 | Amount: 1000-CK-477 |
|---|---|---|

## Attachment A

## Nature of Business

Philips Healthcare (Philips) is a manufacturer of prescription medical devices. Philips' Cambridge, MA location sells devices in the following categories: patient monitors, telemetry, central monitoring station, newborn solutions, electrocardiographs, medical consumables and sensors. No pharmaceutical drug components are associated with these devices to form a "combination" device. No manufacturing or commercial distribution of product occurs from this location. This location is associated with product design as a specification developer as well as serving as a business headquarters with associated administrative functions. The business hours are: 8:00 AM – 5:00 PM, Monday – Friday.

The Cambridge location sells its products to domestic and international customers, including, but not limited to, physicians, distributors, and hospitals. The facility utilizes other locations to physically manufacture and distribute its products. Provided below are the locations that manufacture and distribute:

**Manufacturing Locations:**

Philips Medizin Systeme Böblingen GmbH
Hewlett Packard Strasse 2
71034, Böblingen, Germany
FDA Registration #: 9610816

Philips North America LLC
1001 Murry Ridge Lane
Suite A
Murrysville, PA 15668
FDA Registration #: 3012528160

Philips North America LLC
1003 Corporate Lane
Export, PA 15632
FDA Registration #: 3016701404

Philips North America LLC
9570 Logistics Court
Lockbourne (Columbus), OH 43137
FDA Registration #: 3015464050

Philips Goldway (Shenzhen) Industrial Inc.
No. 2 Kaji North 3rd Road
Nanshan District
Shenzhen, 518057, People's Republic of China
NOTE: Finished goods not distributed in the USA.

**Distributing Locations:**

Philips North America LLC
1003 Corporate Lane
Export, PA 15632
FDA Registration #: 3016701404

Philips North America LLC
9570 Logistics Court
Lockbourne (Columbus), OH 43137
FDA Registration #: 3015464050

Philips Goldway (Shenzhen) Industrial Inc.
No. 2 Kaji North 3rd Road
Nanshan District
Shenzhen, 518057, People's Republic of China
NOTE: Finished goods not distributed in the USA.

Müller - Die lila Logistik Böblingen GmbH
Eugen-Zeyer-Str. 1.
75382, Althengstett, Germany

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[3] Medical Devices[4] Databases[5]

## Establishment Registration & Device Listing

New Search | Back To Search Results

**Establishment:**
Philips North America LLC
**Business Trade Name:**
Philips Medical Systems

222 Jacobs Street
Cambridge, MA 02141
**Registration Number:** 3016618143
**FEI Number*:** 3016618143
**Status:** Active
**Initial Distributor/Importer:** Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
**Date Of Registration Status:** 2023

Verified 7.5.23 BB

**Owner/Operator:**

Philips Medical Systems International BV[6]
Veenpluis 6
Best, NL 5684PC
**Owner/Operator Number:** 1217116[7]

**Official Correspondent:**
Karen Smith
PHILIPS
222 Jacobs Street
Cambridge, MA 02141
**Phone:** 617-6681011

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1217116&OwnerOperatorName=&
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1217116&OwnerOperatorName=&

Page Last Updated: 05/22/2023

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

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U.S. Department of **Health & Human Services**

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1217116&OwnerOperatorName=&
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1217116&OwnerOperatorName=&

## Attachment D

## LLC Information

Philips Healthcare, a division of Philips North America LLC

**Philips Healthcare, a division of Philips North America LLC is wholly-owned by its parent company, Philips Holding USA Inc.**

**LLC Officers:**

**Jeff DiLullo**
*President and Chief Executive Officer*

**Joseph E. Innamorati**
*Vice President and Secretary*

**Ling Liu**
*Vice President and Treasurer*

**Paul W. Cavanaugh**
*Vice President*

**Irma I. Gomez**
*Assistant Secretary*

**Facility Manager:**

**Jeffrey S. DeSanty**
*Director, Complaint Handling Operations*

Enclosed please find a list all site employees.

**Attachment E**

**Delaware Certificate of Good Standing**

# Delaware

The First State



I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "PHILIPS NORTH AMERICA LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-FOURTH DAY OF FEBRUARY, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "PHILIPS NORTH AMERICA LLC" WAS FORMED ON THE SIXTH DAY OF AUGUST, A.D. 1987.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

2134316 8300

SR# 20230692587

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202784530

Date: 02-24-23

**Attachment G**

**Regarding the Resident State License**

Please note that the resident state licensing agency, the Massachusetts Department of Public Health (Department), does not license prescription device manufacturers and distributors. Enclosed please find correspondence from the Department confirming that a license is not required.

An official website of the Commonwealth of Massachusetts Here's how you know

ALERTS | Coronavirus Update

Mass.gov



# Manufacturer and distributor registration information

## Learn about registration for manufacturers and distributors of medical devices and pharmaceuticals.

## Medical device manufacturer and distributor registration

This policy is intended to assist manufacturers and/or distributors of medical devices in Massachusetts to ascertain whether they need to obtain a controlled substances registration from the Massachusetts Department of Public Health (MDPH). Such a controlled substances registration would be required under Massachusetts law and regulation (M.G.L. c. 94C and 105 CMR 700.000) if a company were to manufacture, distribute or dispense controlled substances in the Commonwealth, or possess controlled substances with the intent of manufacturing, distributing or dispensing. Please note that in accordance with Massachusetts law the term "controlled substance" denotes any prescription pharmaceutical (i.e., either a federally controlled substance or a "legend" drug). Thus, any medical device that contains a prescription pharmaceutical is considered to be a controlled substance in Massachusetts regardless of its standing as a medical device.

If you are a manufacturer and/or a distributor in Massachusetts and your company does not manufacture, dispense or distribute controlled substances within the Commonwealth, or possess controlled substances for such purposes your company does not need, and has no basis for obtaining, a controlled substances registration from Massachusetts.

Thus, for example, a manufacturer or distributor of a medical device is not required to register if:

1. the device does not contain any prescription pharmaceutical; or
2. the device does contain a prescription pharmaceutical but is not manufactured, stored, dispensed, or distributed within the Commonwealth.

## Pharmaceutical manufacturer and distributor registration

This policy is intended to assist manufacturers and/or distributors of prescription pharmaceuticals to ascertain whether they need to obtain a controlled substances registration from the Massachusetts Department of Public Health (MDPH). Such a controlled substances registration would be required under Massachusetts law and regulation (M.G.L. c. 94C and 105 CMR 700.000) if a company were to manufacture, distribute or dispense a controlled substance in the Commonwealth, or possess a controlled substance with the intent of manufacturing, distributing or dispensing. Please note that in accordance with Massachusetts law the term "controlled substance" denotes any prescription pharmaceutical (i.e., either a federally controlled substance or a "legend" drug).

If you are a manufacturer and/or a distributor in Massachusetts and your company does not manufacture, dispense or distribute a controlled substance within the Commonwealth, or possess a controlled substance for such purposes your company does not need, and has no basis for obtaining, a controlled substances registration from Massachusetts.

If you are a manufacturer and/or a distributor outside of Massachusetts and your company does not manufacture, dispense or distribute a controlled substance within the Commonwealth, or possess a controlled substance in the Commonwealth for such purposes your company does not need, and has no basis for obtaining, a controlled substances registration from Massachusetts.

Thus, for example, a manufacturer or distributor of a prescription pharmaceutical is not required to register if manufacture, storage and distribution of the pharmaceutical is handled from outside the state and the only activity within Massachusetts is direct delivery to a registered entity in the state.

## CONTACT

### Drug Control Program

### Address

250 Washington Street, 3rd Floor, Boston, MA 02108
Directions

### Phone

(617) 973-0800

## RELATED

**Apply for, renew, or amend information for your facility MCSR**

**Verify an MCSR**

**M.G.L. c. 94C**

**105 CMR 700.00: Implementation of MGL c.94C**



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ACORD®

# CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
01/03/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

| | | |
|---|---|---|
| PRODUCER<br>Marsh USA, Inc.<br>1166 Avenue of the Americas<br>New York, NY 10036<br><br>CN101736188-GAUW-NI-22-23 | CONTACT NAME:<br>PHONE (A/C, No, Ext):<br>E-MAIL ADDRESS: | FAX (A/C, No): |
| | INSURER(S) AFFORDING COVERAGE | NAIC # |
| | INSURER A : National Union Fire Insurance Co Of Pittsburgh | 19445 |
| INSURED<br>Philips North America LLC<br>222 Jacobs Street, 3rd Floor<br>Cambridge, MA 02141 | INSURER B : Safety National Casualty Corp. | 15105 |
| | INSURER C : | |
| | INSURER D : | |
| | INSURER E : | |
| | INSURER F : | |

**COVERAGES** **CERTIFICATE NUMBER:** NYC-011181363-12 **REVISION NUMBER:** 10

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

| INSR LTR | TYPE OF INSURANCE | ADDL INSD | SUBR WVD | POLICY NUMBER | POLICY EFF (MM/DD/YYYY) | POLICY EXP (MM/DD/YYYY) | LIMITS | | |
|---|---|---|---|---|---|---|---|---|---|
| A | COMMERCIAL GENERAL LIABILITY<br>CLAIMS-MADE [X] OCCUR<br>GEN'L AGGREGATE LIMIT APPLIES PER:<br>[X] POLICY [ ] PRO-JECT [ ] LOC<br>OTHER: | | | 536-18-48 | 12/31/2022 | 12/31/2023 | EACH OCCURRENCE | $ | 2,000,000 |
| | | | | | | | DAMAGE TO RENTED PREMISES (Ea occurrence) | $ | 500,000 |
| | | | | | | | MED EXP (Any one person) | $ | 10,000 |
| | | | | | | | PERSONAL & ADV INJURY | $ | 2,000,000 |
| | | | | | | | GENERAL AGGREGATE | $ | 5,000,000 |
| | | | | | | | PRODUCTS - COMP/OP AGG | $ | 5,000,000 |
| | | | | | | | | $ | |
| B | AUTOMOBILE LIABILITY<br>[X] ANY AUTO<br>OWNED AUTOS ONLY [ ] SCHEDULED AUTOS<br>HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY | | | CA6675481 | 12/31/2022 | 12/31/2023 | COMBINED SINGLE LIMIT (Ea accident) | $ | 2,000,000 |
| | | | | | | | BODILY INJURY (Per person) | $ | |
| | | | | | | | BODILY INJURY (Per accident) | $ | |
| | | | | | | | PROPERTY DAMAGE (Per accident) | $ | |
| | | | | | | | | $ | |
| A | [X] UMBRELLA LIAB [X] OCCUR<br>EXCESS LIAB [ ] CLAIMS-MADE<br>DED [ ] RETENTION $ | | | 10-736-193 | 12/31/2022 | 12/31/2023 | EACH OCCURRENCE | $ | 5,000,000 |
| | | | | | | | AGGREGATE | $ | 5,000,000 |
| | | | | | | | | $ | |
| B | WORKERS COMPENSATION AND EMPLOYERS' LIABILITY | | | LDS4047559 (AOS) | 12/31/2022 | 12/31/2023 | [X] PER STATUTE [ ] OTH-ER | | |
| B | ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBEREXCLUDED? (Mandatory in NH) Y/N [N] N/A<br>If yes, describe under DESCRIPTION OF OPERATIONS below | | | PS4047560 (WI) | 12/31/2022 | 12/31/2023 | E.L. EACH ACCIDENT | $ | 2,000,000 |
| | | | | | | | E.L. DISEASE - EA EMPLOYEE | $ | 2,000,000 |
| | | | | | | | E.L. DISEASE - POLICY LIMIT | $ | 2,000,000 |
| A | CYBER LIABILITY | | | 03-932-59-76<br>'Subject to a policy deductible' | 12/31/2022 | 12/31/2023 | Occurrence Limit | | 10,000,000 |
| | | | | | | | Aggregate Limit | | 10,000,000 |

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Additional Certificate Holder: Virginia Community College System Commonwealth of Virginia Virginia Community College System 147 Daleville Centre Drive Daleville, VA 24083.

Evidence of coverage.

**CERTIFICATE HOLDER**

Philips North America LLC
See above for the Complete Cert. Holder Name
222 Jacobs Street, 3rd Floor
Cambridge, MA 02141

**CANCELLATION**

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Marsh USA Inc.

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AGENCY CUSTOMER ID: CN101736188
LOC #: New York

# ADDITIONAL REMARKS SCHEDULE



| AGENCY | NAMED INSURED |
|---|---|
| Marsh USA, Inc. | Philips North America LLC<br>222 Jacobs Street, 3rd Floor<br>Cambridge, MA 02141 |
| POLICY NUMBER | |
| CARRIER / NAIC CODE | EFFECTIVE DATE: |

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Named Insured Includes:
370 West Trimble Road LLC
AllParts Medical, LLC
BioTelemetry, Inc.
BioTel Research, LLC
BioTelemetry Care Management, LLC
Telcare Medical Supply, LLC
Telcare, LLC
Braemar Manufacturing, LLC
Cardiac Monitoring Holding Company, LLC
LifeWatch Corp.
LifeWatch Services, Inc.
Cardiologs Technologies Inc.
CardioNet, LLC
BioTel INR, LLC
Geneva Healthcare, LLC
VirtualScopics, LLC
Blue Willow Systems LLC
Discus Holdings, LLC
Discus Dental, LLC
Discus International, LLC
Discus Dental Canada, LLC
Electrical Geodesics LLC
Cerebral Data Systems, Inc. (CDS)
Intact Vascular, Inc.
Philips CS Corporation (formerly "Vita Topco, Inc." and "Philips Capsule Corporation")
Capsule Technologies, Inc.
CapsuleTech, Inc.
Philips Healthcare Informatics, Inc.
Philips Image Guided Therapy Corporation
Cardioprolific Inc.
Crux Biomedical, LLC
Spectranetics LLC
Volcano Atheromed, Inc.
Philips Medical Systems (Cleveland), Inc.
Philips Medical Systems MR, Inc.
Philips DS North America LLC
Philips North America, LLC
Philips North America, LLC D/B/A Philips Healthcare
Philips Oral Healthcare, LLC
Philips RS North America Holding Corporation
Philips RS North America LLC
Respironics California, LLC
Respironics Colorado, Inc.
Respironics Logistics Services, LLC
Respironics Novametrix, LLC
Philips Semiconductors Inc.
Remote Diagnostics Technologies LLC


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AGENCY CUSTOMER ID: CN101736188
LOC #: New York

# ADDITIONAL REMARKS SCHEDULE



| AGENCY | NAMED INSURED |
|---|---|
| Marsh USA, Inc. | Philips North America LLC<br>222 Jacobs Street, 3rd Floor<br>Cambridge, MA 02141 |
| POLICY NUMBER | |
| CARRIER / NAIC CODE | EFFECTIVE DATE: |

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Respiratory Technologies, Inc.
Tomtec Corporation
TR Management Company, LLC
U.S. Philips Corporation
Vesper Medical, Inc.
VISICU, Inc.
VitalHealth Software Corp.
Wellcentive LLC (formerly "Wellcentive, Inc.")
Wellcentive QR, LLC
American Color & Chemical, L.L.C.
ATL Ultrasound, Inc.
Philips Ultrasound LLC (formerly "Philips Ultrasound, Inc.")
ATL International LLC
Philips Electronics North America Foundation
Philips Electronics Realty, LLC
Philips Medical Systems Export, Inc.
Philips MPEG Inc.
Philips Project Management, LLC


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# NEVADA STATE BOARD OF PHARMACY

**985 Damonte Ranch Pkwy Suite 206**
**Reno, NV 89521**
**(775) 850-1440**
**Fax: (775) 850-1444**

## PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 30185503

Application/License No. _____

*See attached list of principal names (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is *See attached list of principal addresses (Address of Applicant/Principal), as PRINCIPAL, and Western Surety Company (Surety Company), a corporation organized under the laws of the state of South Dakota (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 151 N Franklin Street Chicago, IL 60606 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 21, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

# Western Surety Company

## POWER OF ATTORNEY APPOINTING INDIVIDUAL ATTORNEY-IN-FACT

**Know All Men By These Presents,** That WESTERN SURETY COMPANY, a South Dakota corporation, is a duly organized and existing corporation having its principal office in the City of Sioux Falls, and State of South Dakota, and that it does by virtue of the signature and seal herein affixed hereby make, constitute and appoint Kristin S. Bender

, Individually

of Morristown, New Jersey, its true and lawful Attorney(s)-in-Fact with full power and authority hereby conferred to sign, seal and execute for and on its behalf bonds, undertakings and other obligatory instruments of similar nature

**- In Unlimited Amounts -**

Surety Bond Number: 30185503
Principal: See attached list of principals
Obligee: State of Nevada and Nevada State Board of Pharmacy

and to bind it thereby as fully and to the same extent as if such instruments were signed by a duly authorized officer of the corporation and all the acts of said Attorney, pursuant to the authority hereby given, are hereby ratified and confirmed.

This Power of Attorney is made and executed pursuant to and by authority of the By-Law printed on the reverse hereof, duly adopted, as indicated, by the shareholders of the corporation.

**In Witness Whereof,** WESTERN SURETY COMPANY has caused these presents to be signed by its Vice President and its corporate seal to be hereto affixed on this 2nd day of February, 2021.

WESTERN SURETY COMPANY

Paul T. Bruflat

Paul T Bruflat, Vice President

State of South Dakota }
County of Minnehaha } ss

On this 2nd day of February, 2021, before me personally came Paul T. Bruflat, to me known, who, being by me duly sworn, did depose and say: that he resides in the City of Sioux Falls, State of South Dakota; that he is the Vice President of WESTERN SURETY COMPANY described in and which executed the above instrument; that he knows the seal of said corporation; that the seal affixed to the said instrument is such corporate seal; that it was so affixed pursuant to authority given by the Board of Directors of said corporation and that he signed his name thereto pursuant to like authority, and acknowledges same to be the act and deed of said corporation.

My commission expires
March 2, 2026

M. BENT
NOTARY PUBLIC
SOUTH DAKOTA

M. Bent

M. Bent, Notary Public

**CERTIFICATE**

I, L. Nelson, Assistant Secretary of WESTERN SURETY COMPANY do hereby certify that the Power of Attorney hereinabove set forth is still in force, and further certify that the By-Law of the corporation printed on the reverse hereof is still in force. In testimony whereof I have hereunto subscribed my name and affixed the seal of the said corporation this 21 day of April, 2023.

WESTERN SURETY COMPANY

L. Nelson

L. Nelson, Assistant Secretary

Form F4280-2-2021

**Authorizing By-Law**

## ADOPTED BY THE SHAREHOLDERS OF WESTERN SURETY COMPANY

This Power of Attorney is made and executed pursuant to and by authority of the following By-Law duly adopted by the shareholders of the Company.

Section 7. All bonds, policies, undertakings, Powers of Attorney, or other obligations of the corporation shall be executed in the corporate name of the Company by the President, Secretary, and Assistant Secretary, Treasurer, or any Vice President, or by such other officers as the Board of Directors may authorize. The President, any Vice President, Secretary, any Assistant Secretary, or the Treasurer may appoint Attorneys in Fact or agents who shall have authority to issue bonds, policies, or undertakings in the name of the Company. The corporate seal is not necessary for the validity of any bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation. The signature of any such officer and the corporate seal may be printed by facsimile.

# WESTERN SURETY COMPANY
## Sioux Falls, South Dakota
## Statement of Net Admitted Assets and Liabilities
## December 31, 2021

### ASSETS

| | |
|---|---|
| Bonds | $ 1,940,298,870 |
| Stocks | 19,721,943 |
| Cash, cash equivalents, and short-term investments | 32,146,891 |
| Receivables for securities | 140,000 |
| Investment income due and accrued | 17,433,547 |
| Premiums and considerations | 54,366,110 |
| Amounts recoverable from reinsurers | 3,204,634 |
| Current federal and foreign income tax recoverable and interest thereon | - |
| Net deferred tax asset | 14,565,007 |
| Receivable from parent, subsidiaries, and affiliates | 14,891,869 |
| Other assets | 1,037 |
| Total Assets | $ 2,096,769,908 |

### LIABILITIES AND SURPLUS

| | |
|---|---|
| Losses | $ 214,859,103 |
| Loss adjustment expense | 48,667,258 |
| Commissions payable, contingent commissions and other similar charges | 10,885,216 |
| Other expenses (excluding taxes, license and fees | - |
| Taxes, License and fees (excluding federal and foreign income taxes) | 2,781,662 |
| Federal and foreign income taxes payable | 300,285 |
| Unearned premiums | 263,317,295 |
| Advance premiums | 6,618,279 |
| Ceded reinsurance premiums payable (net of ceding commissions) | 5,081,348 |
| Amounts withheld or retained by company for account of other | 10,237,011 |
| Provision for reinsurance | 6,261,560 |
| Payable to parent, subsidiaries and affiliates | 7,170 |
| Payable on security transactions | 35,226 |
| Other liabilities | 155,189 |
| Total Liabilities | $ 569,206,602 |

| | | |
|---|---|---|
| Surplus Account: | | |
| Common stock | $ 4,000,000 | |
| Gross paid in and contributed surplus | 286,896,195 | |
| Unassigned funds | 1,236,667,111 | |
| Surplus as regards policyholders | | $ 1,527,563,306 |
| Total Liabilities and Capital | | $ 2,096,769,908 |

I, Julie Lee, Assistant Vice President of Western Surety Company hereby certify that the above is an accurate representation of the financial statement of the Company dated December 31, 2021, as filed with the various Insurance Departments and is a true and correct statement of the condition of Western Surety Company as of that date.

WESTERN SURETY COMPANY

By Julie Lee
Assistant Vice President, External Reporting

Subscribed and sworn to me this 14th day of March, 2022.

My commission expires:

"OFFICIAL SEAL"
CHRISTOPHER LOPATOWSKI
Notary Public, State of Illinois
My Commission Expires 01/14/2024

By Christopher Lopatowski
Notary Public

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 21st day of April, 20 23.

APPLICANT/PRINCIPAL

**See attached principal signature page

Authorized Representative

SIGNED and SEALED in the presence of:

Witness

Witness

SURETY COMPANY

Western Surety Company

Surety Company's Representative

Kristin S. Bender, Attorney-in-fact

print name

Nevada Non-Resident Producer License No. 829075

SIGNED and SEALED in the presence of:

Witness Jessica Iannotta

Witness April D. Perez

Countersigned by:

N/A

Nevada Resident Agent

**APPLICANT/PRINCIPALS:**

AllParts Medical, LLC, 400 Brick Church Park Drive, Nashville, TN 37207
Discus Dental, LLC, 1700 A South Baker Ave., Ontario, CA 91761
Philips Healthcare Informatics, Inc., 4430 Rosewood Drive, Suite 200, Pleasanton, CA 94588
Philips Healthcare, a division of Philips North America LLC, 22100 Bothell Everett Hwy, Bothell, WA 98021
Philips Healthcare, a division of Philips North America LLC, 222 Jacobs Street, Cambridge, MA 02141 Philips Ultrasound LLC, 22100 Bothell Everett Highway, Bothell, WA 98021
Philips Image Guided Therapy Corporation, 3721 Valley Center Drive, Suite 500, San Diego, CA 92130
Philips Image Guided Therapy Corporation, 2451 Mercantile Drive, Rancho Cordova, CA 95742
Respironics Logistics Services, LLC, 174 Tech Center Drive, Suite 200, Mt. Pleasant, PA 15666
Spectranetics LLC, 9965 Federal Drive, Colorado Springs, CO 80921
Visicu, Inc., 217 E. Redwood Street, Suite 1900, Baltimore, MD 21202

Paul Cavanaugh
Authorized Representative - [redacted] Paul Cavanaugh
Witness
Witness

Philips RS North America LLC, 1010 Murry Ridge Lane, Murrysville, PA 15668
Philips RS North America LLC, 174 Tech Center Drive, Suite 100, Mt. Pleasant, PA 15666

Authorized Representative - Stuart Cashman
Witness
Witness

Philips RS North America LLC LIMITED LIABILITY COMPANY SEAL 1984 DELAWARE

DISCUS DENTAL LLC LIMITED LIABILITY SEAL 2007 CALIFORNIA COMPANY

PHILIPS NORTH AMERICA LLC LIMITED LIABILITY SEAL 1987 DELAWARE COMPANY

PHILIPS ULTRASOUND LLC LIMITED LIABILITY SEAL 1973 WASHINGTON COMPANY

SPECTRANETICS LLC LIMITED LIABILITY SEAL 1988 DELAWARE COMPANY

IMAGE GUIDED THE SEAL 2000

**Attachment H**

**Medical Devices, Equipment and Gases (MDEG) Administrator Form**

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of MDEG: Philips Healthcare, a division of Philips North America LLC  MDEG License # (if applicable): MP01126

Physical Address: 222 Jacobs Street

City: Cambridge  State: MA  Zip: 02141

Mailing Address (if different from physical address): Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover  State: MA  Zip: 01810

Telephone: 617-245-5900  Website: www.usa.philips.com/healthcare

Licensing Company Email: beth.c.rogers@philips.com

**Section 2: Personal Information**

First: Jeffrey  Middle: Scott  Last: DeSanty

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted]  SSN or ITIN: [redacted]  Sex: ☑ M ☐ F ☐ X

Mailing Address: Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover  State: MA  Zip: 01810

Telephone: 617-245-5903  Email: jeff.desanty@philips.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Southern Connecticut State University | | | 09/83 – 12/87 | |
| Address | City | State | Zip | |
| 501 Crescent Street | New Haven | CT | 06515 | |
| Diploma/Degree obtained, if any | | | | |
| B.S., Computer Science | | | | |

| School Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| St Joseph's High School | | | 09/79 – 06/83 | |
| Address | City | State | Zip | |
| 2320 Huntington Tpk. | Trumbull | CT | 06611 | |
| Diploma/Degree obtained, if any | | | | |

| School Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Address | City | State | Zip | |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |

| School Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Address | City | State | Zip | |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |

| School Name | | | From - To (MM/YY – MM/YY | |
|---|---|---|---|---|
| | | | | |
| Address | City | State | Zip | |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 09/21-CURRENT | [redacted] Larson Avenue | Leominster | MA | 01453 |
| 10/07- 09/21 | [redacted] WAGNER LN | Holden | MA | 01520 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Philips Healthcare, a division of Philips North America LLC | | | 08/19 - Present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 222 Jacobs Street | | Cambridge | MA | 02141 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 617-245-5900 | Director, Complaint Handling Operations | | 40 hours per week | |
| **Description of Duties** | | | | |
| Managed a team of individual contributors for worldwide support of complaint operation activities such as new complaint handling employee onboarding, training, complaint process ownership, complaint handling system SME, records review, and continuous improvement of processes, procedures, and tools. | | | | |

N/A

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

Continue on next page if additional space is needed.

N/A

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state? | | ✓ |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline. | | ✓ |

N/A

**Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| | | | | |
| Reason/Charge | | | | |
| | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| | | | | |
| Name of Business/Industry/Entity | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

12/7/2022
Date

I, Jeffrey DeSanty, **certify that as the MDEG Administrator for**

Philips Healthcare, a division of Philips North America LLC,

**that I (initial that you have read and meet the following requirements):**

1. JD Have a high school diploma or its equivalent;
2. JD Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JD Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JD Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Jeffrey DeSanty
Print Name (First, Last)

Jeffrey DeSanty
Original Signature (electronic, copies or stamps not accepted)

12/7/2022
Date

| Board Use Only | Date Received: 7-3-23 |
|---|---|

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

**Section 1: Pharmacy/Wholesaler Information**

Name of Pharmacy/Wholesaler: Philips Healthcare, a division of Philips North America LLC

Pharmacy/Wholesaler License # (if applicable): Pending; current MDEG license #: MP01126

Physical Address: 222 Jacobs Street

City: Cambridge State: MA Zip: 02141

Mailing Address (if different from physical address): Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover State: MA Zip: 01810

Telephone: 617-245-5900 Website: www.usa.philips.com/healthcare

Licensing Company Email: beth.c.rogers@philips.com

**Section 2: Personal Information**

First: Jeffrey Middle: Scott Last: DeSanty

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover State: MA Zip: 01810

Telephone: 617-245-5903 Email: jeff.desanty@philips.com

Are you a citizen of the United States? ■ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Southern Connecticut State University | | 9 83 12/87 | |
| Address | City | State | Zip |
| 501 Crescent Street | New Haven | CT | 06515 |
| Diploma/Degree obtained, if any | | | |
| B.S., Computer Science | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| ST. JOSEPHS HIGH SCHOOL | | 9 79 + 6/83 | |
| Address | City | State | Zip |
| 2320 HUNTINGTON TPK | TRUMBULL | CT | 06611 |
| Diploma/Degree obtained, if any | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 09/21 - CURRENT | [redacted] Larson Avenue | Leominster | MA | 01453 |
| 10/07 - 09/21 | [redacted] WAGNER LN | HOLDEN | MA | 01520 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Philips Healthcare, a division of Philips North America LLC | | | 08/19 - Present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 222 Jacobs Street | | Cambridge | MA | 02141 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 617-245-5900 | Director, Complaint Handling Operations | | 40 hours per week | |
| **Description of Duties** | | | | |
| Managed a team of individual contributors for worldwide support of complaint operation activities such as new complaint handling employee onboarding, training, complaint process ownership, complaint handling system SME, records review, and continuous improvement of processes, procedures, and tools. | | | | |

N/A

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
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| **Description of Duties** | | | | |
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| Business Name | | | From - To (MM/YY – MM/YY) | |
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| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

Continue on next page if additional space is needed.

N/A

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | N/A | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✓ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✓ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✓ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

N/A

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| | | | | |
| Reason/Charge | | | | |
| | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| | | | | |
| Name of Business/Industry/Entity | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

12/7/2022
Date

I, Jeffrey DeSanty, **certify that as the designated representative for**

Philips Healthcare, a division of Philips North America LLC,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. JD I am at least 21 years of age;
3. JD I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JD I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JD I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JD I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JD I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jeffrey DeSanty
Print Name (First, Last)

Jeffrey DeSanty
Original Signature (electronic, copies or stamps not accepted)

12/7/2022
Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Jeffrey DeSanty

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/7/2022

Date

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**Please have this section completed in the presence of a Notary Public.**

State of Massachusetts, ss. County of Worcester

I, Jeffrey S. DeSanty, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

12/7/2022

**Date**

Subscribed and Sworn to before me this 7 day of December 2022

**Notary Public Signature**

DAISY Y AYALA
Notary Public
COMMONWEALTH OF MASSACHUSETTS
My Commission Expires
February 10, 2023

(Seal)

## Employee List

Aaron Hillman
Abdur Sher
Abhiram Desai
Ada Nemira
ADAM DESJEAN
Adam Mossey
Aditya Sirohi
Adnane Benali
Adrienne Smith
Ahmad Saeed
Aidan Burbridge
Aidi Moubhij
Akash Bhimani
Akosua Kwaa
Alan Law
Aleksandra Soltamova
Alex Barga
Alex Ginzburg
Alex Jablenski
Alexander D'Haeseleer
Alexander Schreivogel
Alexander Tang
Ally Kizner
Lexie Reed
Alexandru Patriciu
Alexis Henry
Alexys Scott
Alicia Coleman
Alicia Finnegan
Alison Jimerson
AJ Ricabo
Allyson Hartzell
Altemar Melendez
Alvin Chen
Alvin Naidoo
Alwin Thomas
Amanda Anderson
Amanda Berriola
Amanda Lamarche
Amin Feizpour
Amir Abdolahi
Amira Tokatli
Amirtha Babu
Amisha Gupta
Amittai Shapira
Amy Hayes
Amy Raicsics
Andrea Frassine
Andy Knapp
Andrei Lutai
Andrew Arthur
Andrew Bambury
Drew Cameron
Andy Donati
Andy Kim
Andrew LeClair
Andrew Mulholland
Andrew Szurley
Andrew Urban
Andrew Yee
Ankita Chauhan
Ann Moynihan
Anna Duzenko
Anna Gatilova
Anna Kahn
Annamalai Natarajan
Anne Greiner
Anne Pearlman
Anne Salemme
Annette Zola
Annie Yan
Anthony Bonaccorsi
Antonio Espinoza
Antonios Bousios
Anumod Odungattu Thodiyil
Arad Lajevardi-Khosh
Archana Jeyaram
Arian Iraqi
Art Queenan
Arvind Subramanian
Asal Naraghi
Ashish Agarwal
Ashish Chaudhari
Ashish Dass
Ashish Panke
Ashley Davidson
Ashley Dickerson
Atul Nipane
Augusta Ginsburg
Aurelie Beeuwsaert
Avani Pandya
Avi Dines
Avi Pinhasi
Aziz L'Bahy
Bach-Son Dinh
Balaji Sivakumaran
Balasubramanian Naganathan
Balasundar Raju
Bandana Kumar
Bea Mitchell
Ben Bailey
Benjamin Kuris
Ben Tong
Benoit Mory
Benvindo J. Santos
Bertan Hallacoglu
Betza Bravo
Bev Schaen
Bhanu Suryadevara
Bharathi Chaparala
Bidur Dhaul
Bijoy Rayaroth
Bin Liu
Anne Ren
Binling Chen
Braeden Sanford

Brandi Segala
Brenda Briones
Brenda FitzPatrick
Brendan OConnell
Brian Collamore
Brian Dunbar
Brian Kim
Brian Landy
Brian Lee
Brian Mandrik
Brian McLaverty
Brian Norman
Brian O'Leary
Brian Rosnov
Brianna Fitzgibbons
Bruce Johnson
Brundha RamMohan
Candace Pagliccia
Candice Downs
Cara Lane
Carina Becker
Carlos Mimoso
Carol Morrissey
Carol Shaughnessy
Cassandra Price
Catherine Barrett
Catherine Gauthier
Catherine Quinn
Cathy Li
Causby Lewis
Cecilia Meijer
Celeste Greenbaum
Charles Mosher
Charles Pitt
Charlie Warrington
Chester Phillips
Cheuw Lee Yeo
Christina Chow
Christina Kavanagh
Christina McWilliams
Christine Berard
Christine Brooks
Christine Caetano
Christine Wright
Christoph Pedain
Christophe Dore
Chris Anderson
Chris Barrett
Christopher Boit
Chris Bonis
Christopher Haverstock
Chris Kenyon
Chris Orbon
Chris Wheeler
Chris Yee
Christopher Yorke
Chuan Zheng
Tracy Wang
Claire Arakaki
Clare Howe
Clare Jessey
Claude Gomolka
Clive Everett
Cody Fitzgerald
Colin Conte
Connie Franklin
Kees Cruijsen
Craig Carpenter
Craig Nuttall
Craig Stafford
Cindy McDonough
Cyrille Martin
Daeri Coskren
Daisy Zhou
Dan Jiang
Danay DePierre
Daniel Araniz
Daniel Giacalone
Dan Jordan
Daniel Jordan
Daniel Sullivan
Daniel Lee
Daniel Marrara Bertholdo
Daniel Mcfarlane
Daniel Milewski
Daniel Youkana
Danielle Jordan
Darrin Milner
Darshan Bhojani
Dave Blackmun
David Crockford
David Daggett
David DiNatale
David Hoberman
David Huynh
David Huynh
Dave Knapp
David Mackey
David Morgan
David Noren
David Phillips
David Ruthven
David Wright
Dawn Bomba
Dawn Mahoney
Dawn McCafferty
Dayton Schlosser
Debayan Biswas
Deb Hanlon
Deborah Matthews
Deborah Pacunas
Deborah Roux
Deborah Spivack
Deepa Naik
Deepak Kumar
Delwin Villarante
Denis Desrochers
Denise Norman
Derek Dodge
Derek Marcotte
Derek Verhoorn
Devin Mahoney
Dhananjay Sonawane

Dhiraj Pisal
Diana Sherlock
Diane Santomassimo
Diego Carlesso
Dmytro Aviedov
Do Hyung Kim
Donald Gallant
Donna Poulin
Donna Reid
Dora Ketola
Douglas Hoover
Drishti Goda
Edward Ahigian
Ed Goss
Edward Moreno
Ted Phelps
Ed Ryan
Ted Schantz
Edward Trant
Katerina Fialkovskaya
Elaine Fong
Elaine MacFarlane
Elissa Spinner
Liz Bastos-Buck
Elizabeth Bunal
Beth Demers
Liz Gordon
Elizabeth Herbst
Elizabeth Leonard
Elizabeth O'Dowd
Ellen Silveira
Elrina Mendonca
Els Vandecandelaere
Emerson Portes
Emily Geras
Emily Moore
Emily Smith
Emma Ledesma
Emma Smith-Otitoju
Emmanuele Salvati
Eric Atherton
Eric Marino
Eric Monreal
Erik Eldracher
Erik Heckman
Erik Houbolt
Erik-Jan Peerbolte
Erin Monzione
Erin Murphy
Erina Ghosh
Esther Kin
Eva Macari
Lia Koumbaridou
Fanny Graham
Farhan Chughtai
Francesco Vicario
Francis Kim
Frank Makie
Franck Fleury
Francois Drapeau-Paquin
Fred Borgenicht
Fred Dolloff
Gabe Mankovich
Gail Darcey
Gail Fox
Gail Greenblatt
Gary Burns
Gaurav Gandhi
Gautam Shah
Geert Lievens
Gemma Roddy
George Cooper
George Thissell
George Tutu
Geri McCarthy
Gerard Cnossen
Ghassan Bahou
Girish Sripathi
Glenn Faucher
Gosse Rienks
Goutam Ghoshal
Grace Hanson
Grace Landry
Gregory Raber
Han Siong Ngan
Hannah Miller
Aaron Wang
Harini Venugopal
Harpreet Tehim
Harshdeep Singh
Heather Morton
Helen Wilson
Hendrik Mandelkow
Alec Cheng
Henrietta Musa
Hinesh Surati
Hisham Elzayat
Hua Xie
Hugh Wyman
Huiling Zhang
Hyeonwoo Lee
Ian Carraher
Iason Zacharias Apostolakis
Ikaro Silva
Irma Gomez
Islam Alsarabi
Jack Guo
Jaclyn Smith
Jake Goroshko
Jake Loewen
Jacques Picard
Jagdeo Lokhande
Jaime FloresQuero
Jaime Osborn
Jim Bruetsch
James Casella
James Durchak
James Kang
Jim Kennedy
Dusty Leppert
Jim McGimpsey
Jim Psiakis
James Richard

James Robinson
James T. McGuinness
James Turner
James Winslow
Janeen McCormick
Jared Boyd
Jason Artis
Jason Baker
Jason Davenport
Jason Shiepe
Jason Tabor
Jason Xiao
Jason Yu
Jaswin Hargun
Javad Fotouhi
Jay Perkoski
Jean Sarkis
Jean-Luc Robert
Jeanette Montgomery
Jeannie O'Leary
Jeffrey Corliss
Jeffrey Croteau
Jeff Genest
Jeffry Flores
Jade Almaso
Paola Florez
Jenna Gilberti
Jennifer Carney
Jennifer Law
Jenn Murphy
Jennifer Roberts
Jennifer Werner
Jennifer Wyse
Jeremy Yan
Jessica Durney
Jessica Kerch
Jessica Paquette
Jessica Valkenburg
Jess Wang
Jessica Yu
Jewel Ascano
Jia Wang
Jianwen Wang
Jiewen Wang
Jill Mcmanus
Jillian Saxon
Jin Liang
Jinming Chen
Jo Seidler
Joann McGimpsey
Joanne Foster
Joanne Lauria
Joanne Ross
Joao Pedro Garcia
Joao Pedro Santiago Rodrigues
Jochen Kruecker
Joel Cervantes
Joey Ouk
John Araujo
John Barga
Joao Cabral
John Cassidy
John Goense
John Hoyt
John Judy
Mark Kolenik
John Larson
John Macmullin
John Maloney
John Medeiros
JP Memon
John Milne
John Murphy
John Pantano
John Ryan
John Waugh
Jon Pallazola
Jon Rawlins
Jonathan Alelis
Jonathan Glazier
Jonathan Golden
Jonathan Hahn
Jon Lizotte
Jonathan Sutton
Jordan Michael
Jorge Segovia
Jose Belarmino
Joe Emilio
Joe Fernald
Joe Giglotto
Joseph Jayakar Nalluri
Joe McMahon
Joe Perry
Joe Richard
Joe Rock
Joshua Cairns
Joshua Racine
Joshua San Juan
Josie Stephen
Juan Diaz Rodriguez
Judy Newell
Judy Lynch Schuster
Judy Tang
Julianna Anthony
Julie Korn
Julie Milner
Julie O'Brien
Julie Weissman Havsy
Junmo An
Justin Beaulieu
Justin Dooley
Justin Ferrullo
Justin Korn
Justin Szeto
Justine Lohrey
John Wang
Kai Moy
KJ Naul
Kara Stephan
Karen Downey
Karen Henderson
Karen Houseton

Karen Mullings
Kareng Pena Sanchez
Kartik Sharma
Katelyn Healey
Kate Hayes
Kathleen Asher
Kathy Lyall
Kathy O'Reilly Larmand
Katy Cianelli
Kathryn Kendall
Katie McNamara
Katie Tippey
Katrina Bennett
Kayla Mitchell
Kelly Dickson
Kelly Fisher
Kelly Gilgen
Kelly McInnis-Pasciuto
Kelly Resco-Summers
Ken Cordio
Ken Peters
Keri Ibbitson
Keri Tuttle
Kerry Mcmullen
Keva Smith
Kevin Coughlan
Kevin Feeney
Kevin Flemming
Kevin Levesque
Kevin Nerheim
Kevin Pacheco
Kevin Pelletier
Kexin Ding
Khaled ElMahgoub
Kimberley Laris
Kimberly Frank
Kimberly Plevock Firth
Kiran Challapali
Krishna Kumar A
Kristen Mather
Kristen Perry
Kristin Cusolito
Kris McQuaid
Kristine Fortin
Krystyna Niklarz Epstein
Kshitij Zutshi
Kate Hu
Kyle Borton
Kyle Clarke
Kyle Nolan
Kyle Vice
Kyle Wildgen
Lakshitaa Sharma
Lasith Adhikari
Laura Hays
Laura Hubelbank
Laura Sammon-Bauchman
Lauren Berry
Lauren DiMuzio
Lauren Hopper
Lauren Rogozinski
Larry Coblentz
Andie Wang
Lei Wang
Leila Kalantari
Leili Salehi
Tad Keach
Lesly Fotso
Li Chen
Lia Haley
Liam Coulter
Jessica Baginski
Lilly Sharma
Lily Berger
Linda Harvey
Lindsay Carlson
Ling Li
Ling LIU
Lynn Wang
Lisa Aach
Lisa Bender
Lisa Thompson
Lisheng Gao
Lois Preckol
Lori Medugno
Lorraine Barber-Miller
Louis Culot
Louis Atallah
Ellie Chase
Louise Mehm
Lucas Oliveira
Luciano Arnold
Lucinda Stabolitis
Lucy McDonough
Luke McCann
Luoluo Liu
Lynn DiMauro
Lynn Gentle-Barry
Mallika Rangan
Man Ching Cheung
Man Nguyen
Manasi Chachad
Mandy Baumgardner
Manognya Sripathi
Marc Mandigers
Marcelo Sieburger
Marcin Balicki
Marco Perez Cuello
Marek Bartula
Marek Szczygiel
Margaret Marcoux
Margaret Messelaar
Daisy Morin
Maria Defreitas
Maria Lopez
Mario Amico
Marisela El Ghali
Marius Precup
Mark Buchalter
Mark Emma
Mark Hollyer
Mark Lang
Thilo Hamann

Mark Wilson
Mark Zaleski
Martha Mcpartlin
Mary Kate Angell
Mary Fortunato-Habib
Mary Kate Kerins
Maggie Singh
Mateo Kocaj
Matt Templeton
Matt Catabia
Matthew Chan
Matthew Hannequin
Matthew Hegarty
Matthew Keller
Matt McCann
Matt Rogovitz
Maureen Johnston
Meera Mathews
Meet Vora
Meg Madison
Meghan Egan
Melissa Woo
Melina Shi
Meredith Reynolds
Mia Bartolomeo
Micah-Shalom Kesselman
Michael Callahan
Michael Cassarino
Michael Comeau
Michael Dolan
Michael Haffey
Mike Hoar
Mike King
Michael Kohlbrenner
Michael Lebrun
Michael Lee
Michael Marquis
Michael Messina
Michael Nakagawa
Michael Perkins
Michael Prak
Michael Raitt
Michael Sarro
Mike Swackhamer
Michael Tavilla
Michael Tourville
Michela Deck
Michele Fasano
Mili Parikh
Minh Tran
Mo Banerjee
Moe Elbaz
Mohsen Zahiri
Molly Donovan
Molly Flexman
Monica Little
Monique Mozone
Montgomery Cole
Morgan Kelley
Morteza Moazami Goudarzi
Muhamed Abdulrahman
Mukul Bichkar
Murat Senel
Myriam Turcotte
Nader Ashtiani
Nancy Loughlin
Nancy Maroney
Nancy Mogge
Natalie Scully
Nataliya Todor
Nathan Harrington
Navdeep Gupta
Naveen Balaraju
Neil Faria
Nemo Nguyen
Nick Braithwaite
Nick Morwood
Nick Pappas
Nick Vigorito
Nichole Quinn
Nicolas Yanez
Nicole Anagnostaras
Nicole Blongiewicz
Nicole Mackenzie
Nicole Vient
Nils Rotgans
Nishima Maini
Noel Denice
Noy Mizrachi
Oliver Brueggemann
Olivia Hecht
Omar Quintero
Omonigho Adebiyi
Pamela Collins
Pamela Toppi
Parastou Eslami
Patricia Ash
Patricia Carey
Patricia Lay
Patricia Morabito
Patrick Lee
Paul Dacosta
Paul Dougherty
Paul Fick
Paul Kamens
Paul Kamisky
Paul Knowles
Paul Laurino
Paul Vernucci
Payaal Patel
Penny Ramjattan
Peng Cui
Perry Conrad
Peter Kung
Peter Ottinger
Philip Keenan
Phillip Pham
Phillip Tomlinson
Piotr Kaczmarek
Po Tse
Pramod Mayigowda
Prasad A V
Praveena Naduthota

Preetham Gaddam
Pritam Kumar
Priyam Patel
Purvi Desai
Qingyan Yu
Quang tran
Rachel McCauley
Radhika Deshpande
Radhika Rajesh Gathia
Raghavendra Srinivasa Naidu
Raghunath Reddy Arava
Raghunath Tupil
Raja Kathirvel
Raj Kanapathy
Raksha Israni
Ralf Viola
Rama Behara
Ramon Erkamp
Raquel Gabrielli
Rashid Al Mukaddim
Ravi Kulbhushan
Ravikumar Maikandan
Rebecca McCarty
Regina Shepler
Renata Janus
Rhonda Lemmo
Richard Alff
Richard Andrews
Richard Gregg
Rick Haggerty
Richard Mccoy
Richard Paglia
Rich Wilmot
Richie Ren
Rishi Goswamy
Rishi Saurabh
Riva Ille
Robert Chalmers
Robert Connelly
Robert Damiano
Rob DeMar
Robert Feuersanger
Robert Fritz
Robert Gamble
Robert Spadafora
Robert Lyons
Robert Moran
Robert Oliver
Rob Snyder
Robert Wall
Roberta Kilfoyle
Robin Niemaszyk
Robin Pizzi
Rohit Gomashe
Rohit Sharma
Roland Telson
Roman Jaquez
Roman Pichardo
Cathy Zou
Rose Mary Murphy
Roslyn Scangas
Ross McGurn
Grace Hsiao
Ruby Brown
Rupinder Hargun
Russell Gallant
Ryan Feuquay
Ryan Hurley
Ryan Kennedy
Ryan Masciarelli
Ryan Mitchell
Saba Ahmed
Sabyasachi Roy
Sachin Chaudhari
Sachin Dahiya
Sachin Munjal
Sameer More
Samer Haidar
Samiah Dunac
Sam Shrift
Samuel Vacheret
Sandeep Dalal
Sandhya Kalkunte
Sandra Allen
Sandy Bistany
Sandra Diprima
Sandra Holmes
Sandy Mitchell
Sandy Callwood
Sanidhya Ravikumar
Sanjay Hegde
Sanjay Singh
Sanjog Misra
Sanket Ghanmare
Sanketh Moudgalya
Santhosh Kumar Krishna Prasad
Santosh Phatarpekar
Sapna Rao
Sara Dolcetti
Sara LaFauci
Sara Mariani
Sarah El-Guindy
Sarah Lee
Saralyn Marquis
Sarath Anchuri
Bamiela Sankaran
Sasi Kiran Rajulapati
Satyavathi Kota
Sayeh Niayesh
Scott Granger
Scott Kline
Sean Delea
Sean Flannery
Sean Kyne
Sebastian Jelinski
Ali Sadeghi
Anand Yadav
Shane Tornifoglio
Shaniqua Clark
Shannon O'Toole
Shannon Ploude
Shari Franzetta

Sharon Downs
Sharon Healey
Shashank Shekhar
Sheila Geiger
Shelby Ohop
Shijo Joseph
Shikha Mehta
Shikimah Harrigan
Shipra Sharma
Shreya Divatia
Shubham Patil
Shubhangi Maheshwari
Sham Sokka
Shyam Bharat
Silpa Das
Silvie Casanova
Simon Abdallah
Simone Hall
Simone Valois
Sina Zarei
Siva Chaitanya Chaduvula
Snehal Chavan
Soheil Borhani
Sokunna Chen
Sonia Rawal
Sophia Sola
Sowmya Senani
Sreelatha Midde
Sridhar Pola
Nick Srinath
Srinivas Somasundaram
Srinivasa Malisetty
Stacey Bakaj
Stefan Jockusch
Steffen Epple
Stephanie Cahill
Stephanie Colman-Brochu
Stephen Heath
Stephen Schmidt
Steve C de Baca
Steven Dickey
Steve Groen
Steve Harutunian
Steve Kelleher
Steven King
Steven Liffmann
Steven Maynard
Steven Mcgrew
Steven Pritchard
Sudeep Koppolu
Sulip Goswami
Sumakshi Mandal
Suman Mondal
Sunny Alam
Suraj Sharma
Sue Bettencourt
Susan Frankfort
Susan Obendorf
Susan Russo
Susanne Poschmann
Sushant Sehgal
Suzanne Kavanagh
Suzanne Smith
Sydney Lang
Sydney Stofflet
Syed Naseer Ahmed
Tais Fogerty
Takahiro Kiritoshi
Taky Djarou
Tara Flanagan
Tarun Anbarasu
Tatiana Shmeleva
Temitope Fetuga
Carlos Bejar-Colonia
Thanh Tran
Theresa Earle
Terry Kirrane
Tom Chauvin
Tom Gatlin
Thomas Karimpanal
Tom Kinahan
Tom King
Tom LaRoche
Tom Mitchell
Thomas Pappas
Thomas Perry
Thom Smith
Tamsin Rogers
Philip Chu
Tiankai Wang
Tieyu Li
Tim Nachbauer
Tim Dalmata
Ting Feng
Todd Borkowski
Todd Jackson
Todd Johnson
Todd McNitt
Tom Hoskinson
Tongxi Wang
Torre Bydlon
Trent Stoddard
Trevor Haubert
Tristan Wentworth
Tyler Gustafson
Umesh Jain
Nia Michael
Nandini Raghavan
Vaidehi Supatkar
Valerie Moger
Vance Grazio
Venkata Damaraju
Victor Carmona
Vihanga Sakpal
Vijay Beedkar
Vikas Sangwan
Vipul Pai Raikar
Ginny Busta
Virginia Honig
Vivian Ramirez
Vu Nguyen
Alex Tan
Wei Zong

Will Zhou
Wendy Demoracski
Wendy-Beth Minton
William Clark
William Cumming
Bill Heffernan
William Shi
Bill Trefethen
Win Nelson
Fay Pu
Xiaowei Li
Sharie Huang
Cindy Wang
Xin Yang
Xin You
Xing Li
Xinni Chen
Yale Chang
Jamex Xu
Yansha Gao
Yavuz Karaman
Gary Li
Yee Him Cheung
Jessy McMillon
Melanie Huang
Yi You Mei
Yebin Gong
Sarah Song
Yolanda Zhou
Yu-He Zhang
Yusheng Liu
Yuxin Rao
Zachary Kinnaird
Zeping Zhu
Zimo Song
Ziqin Shi

# 4R

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

**Non-Refundable $1,000 Fee**

Rev (05/12/2022)

| Where is the facility located? | | ☐ Nevada ☑ Out-of-State |
|---|---|---|
| **Type of Application (check applicable box)** | | **Wholesaler Business Type (check applicable box)** |
| ☑ New Wholesaler<br>☐ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH Current MDEG License #: MP01355 | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: Philips Image Guided Therapy Corporation

Physical Address: 2451 Mercantile Drive

City: Rancho Cordova State: CA Zip: 95742

Mailing Address (if different from physical address): Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover State: MA Zip: 01810

Telephone: 916-638-8008 Website: www.usa.philips.com/healthcare

Name of Designated Representative (DR): Jonathan B. Laosiri

Licensing Company Email: beth.c.rogers@philips.com DR Email: Jonathan.Laosiri@philips.com

| Entities the Wholesaler will Serve (✓ all applicable) | Products to be Handled or Wholesaled (✓ all applicable) | Type of Wholesaling (✓ all applicable) |
|---|---|---|
| ☐ Pharmacies | ☐ Dangerous Drugs | ☐ Manufacturer |
| ☑ Practitioners | ☐ Controlled Substances | ☐ Repacker |
| ☑ Hospitals | ☑ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ☐ Wholesalers | ☐ Others: | ☐ Warehouse |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ☐ Others: | | ☑ Others: Own Label Distributor |

| Section 2: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | X |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | X |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | X |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | X |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | X |

N/A

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

Date

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: N/A - No pharmaceuticals products are handled or sold. See Attachment A.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

N/A

**Section 4: Publicly Traded Corporation**

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: Delaware

Parent Company (if any): Philips Holding USA, Inc.

Corporation/Organization Name: Philips Image Guided Therapy Corporation

Mailing Address: Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover State: MA Zip: 01810

Telephone: 973-659-4484 Email: beth.c.rogers@philips.com

Contact Person Name: Beth C. Rogers

N/A

**Section 6: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A

**Section 7: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | X |
| N/A 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | X | |
| 1. Copy of FDA registration See Attachment B<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment C | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partnership | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** See Attachment D | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** N/A | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** See Attachment D | | ✓ | | |
| • **List of all partners and their percent ownership.** N/A | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment E | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment F | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - Wholly-owned by parent company, Philips Holding USA, Inc. | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** N/A | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) N/A | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment D | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment G | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ See Attachment H | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). See Attachment I | ✓ | ✓ | ✓ | ✓ |
| N/A **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%207-1-19.pdf | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Philips Image Guided Therapy Corporation

Facility Name

Jonathan B. Laosiri

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

9/19/22

Date

| Board Use Only | Date Received: 5-11-23 | Amount: 1000.00 CK-9585 |
|---|---|---|

## Attachment A

## Nature of Business

Philips Image Guided Therapy Corporation (PIGTC) is an FDA-registered manufacturer of prescription devices. PIGTC's products are manufactured by its facility in Costa Rica or by a contract manufacturer. Products are then shipped from its Mercantile Drive, Rancho Cordova, CA facility to its customers (physicians and hospitals). The Mercantile Drive facility's hours of operation are Monday – Friday, from 8:00 a.m. – 5:00 p.m.

Provided below are the manufacturing and distribution locations:

**Manufacturing Locations:**

Philips Image Guided Therapy Corporation
Coyol Free Zone and Business Park, Building B37, Coyol Alajuela, Costa Rica

Volcano AtheroMed, Inc.
1530 O'Brien Drive, Suite A, Menlo Park, CA 94025

**Distributing Location:**

Philips Image Guided Therapy Corporation
2451 Mercantile Drive, Rancho Cordova, CA 95670

FDA

FDA Home[3] Medical Devices[4] Databases[5]

## Establishment Registration & Device Listing

New Search Back To Search Results

**Establishment:**
VOLCANO CORPORATION
**Business Trade Name:**
Philips Image Guided Therapy Corporation

2451 Mercantile Drive
Rancho Cordova, CA 95742
**Registration Number:** 2939520
**FEI Number*:** 2939520
**Status:** Active
**Initial Distributor/Importer:** Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
**Date Of Registration Status:** 2023

**Owner/Operator:**

Philips Medical Systems International BV[6]
Veenpluis 6
Best, NL 5684PC
**Owner/Operator Number:** 2939520[7]

**Official Correspondent:**
Megan Olen
Philips
9965 Federal Drive
Colorado Springs, CO 80921
**Phone:** 719-4472592

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2939520&OwnerOperator
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2939520&OwnerOperator

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Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
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5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases

FDA

FDA Home[3] Medical Devices[4] Databases[5]

## Establishment Registration & Device Listing

New Search Back To Search Results

**Establishment:**
VOLCANO CORPORATION
**Business Trade Name:**
Philips Image Guided Therapy Corporation

2451 Mercantile Drive
Rancho Cordova, CA 95742
**Registration Number:** 2939520
**FEI Number*:** 2939520
**Status:** Active
**Initial Distributor/Importer:** Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
**Date Of Registration Status:** 2022

**Owner/Operator:**

Philips Medical Systems International BV[6]
Veenpluis 6
Best, NL 5684PC
**Owner/Operator Number:** 2939520[7]

**Official Correspondent:**
Megan Olen
Philips
9965 Federal Drive
Colorado Springs, CO 80921
**Phone:** 719-4472592

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&RegNum=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2939520&OwnerOperator
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&RegNum=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2939520&OwnerOperator

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5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&RegNum=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2939520&OwnerOperator

**Attachment D**

**Corporation Information**

Philips Image Guided Therapy Corporation

**Philips Image Guided Therapy Corporation is wholly-owned by its parent company, Philips Holding USA Inc.**

**Corporate Officers:**

**Christopher Landon**
*President*

**Ling Liu**
*Vice President*

**Paul Cavanaugh**
*Vice President*

**Joseph E. Innamorati**
*Vice President and Secretary*

**Scott Moore**
*Vice President and Treasurer*

**Irma I. Gomez**
*Assistant Secretary*

**Directors:**

Ling Liu
Joseph E. Innamorati

**Facility Manager:**

**Jonathan B. Laosiri**
*Manager, Rancho Cordova MFG Operation*

Enclosed please find a list of all site employees.

# Delaware

The First State



*I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "PHILIPS IMAGE GUIDED THERAPY CORPORATION" IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWELFTH DAY OF MAY, A.D. 2023.*

*AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.*

*AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "PHILIPS IMAGE GUIDED THERAPY CORPORATION" WAS INCORPORATED ON THE TWELFTH DAY OF JANUARY, A.D. 2000.*

*AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.*

Jeffrey W. Bullock, Secretary of State

3155105 8300

SR# 20232008637

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203337014

Date: 05-12-23

## Barbara Blackburn

**From:** FDB MedDevice <FDBMedDevice@cdph.ca.gov>
**Sent:** Monday, June 26, 2023 10:57 AM
**To:** Barbara Blackburn
**Subject:** RE: Medical Device Manufacturing License

**WARNING** - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Hello,

Thank you for contacting the California Department of Public Health – Food and Drug Branch. In reference to your inquiry, we do not have an online verification system at this time.

According to our database, the license number mentioned below has an expiration date of 02-19-2025 and an issue date of 02-19-2023. Therefore this license is valid.

Please let us know if you have any further questions or concerns.

Thank you,

HSL
Verfication
Expiration
2-19-2025

FDB Med Device
+1 (916) 650-6500
FDBMedDevice@cdph.ca.gov

**From:** CDPH FDB Food <FDBFood@cdph.ca.gov>
**Sent:** Monday, June 26, 2023 10:51 AM
**To:** FDB MedDevice <FDBMedDevice@cdph.ca.gov>
**Subject:** FW: Medical Device Manufacturing License

Please respond directly from your inbox to the below requestor regarding the inquiry that was submitted through the CDPH FDB Food inbox. When you respond, **PLEASE**, do not respond "Reply all" as the CDPH inbox does not need to be cc'd or included in the correspondence. Thank you!!

*Kelly Tasista*
Department of Public Health
Food & Drug Branch
Food Program support Unit
1500 Capitol Avenue, MS 7602
Sacramento, CA 95814
Email: Kelly.Tasista@cdph.ca.gov
Have an AMAZING day!! 😊

**From:** Barbara Blackburn <bblackburn@pharmacy.nv.gov>
**Sent:** Monday, June 26, 2023 10:34 AM

**To:** CDPH FDB Food <FDBFood@cdph.ca.gov>
**Subject:** Medical Device Manufacturing License

**This Message Is From an External Sender**
This message came from outside your organization.

Report Suspicious

The Nevada Board of Pharmacy is attempting to use the FDB website to search for a Medical Device Manufacturing License for verification purposes but cannot locate the search option.

We are looking for Philips Image Guided Therapy Corporation- License 111118
We need to verify the current expiration date.

Thank you in advance for assistance.

Barbara A. Blackburn
Licensing Specialist

**Nevada State**
**Board of Pharmacy**
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
Office: 775-850-1440 Ext. 131
Fax: 775-850-1444
Web Page: www.bop.nv.gov

# STATE OF CALIFORNIA

## DEPARTMENT OF PUBLIC HEALTH
## FOOD AND DRUG BRANCH

## MEDICAL DEVICE MANUFACTURING LICENSE

Philips Image Guided Therapy Corporation
2870 Kilgore Raod,
2451 Mercantile Drive
Ranch Cordova, CA 95742

**LICENSE NUMBER: 111118**
**EXPIRATION DATE: 2/19/2023**

The person named herein is licensed to manufacture devices through the expiration date of this license. This license is issued in accordance with the provisions of Division 104, Chapter 6, Article 6 of the California Health and Safety Code and is not transferable to any other person or place. The licensee is required by law to immediately notify the California Department of Public Health of any change in the information reported in the application.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

ACORD®

# CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
01/03/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

| | | |
|---|---|---|
| PRODUCER<br>Marsh USA, Inc.<br>1166 Avenue of the Americas<br>New York, NY 10036<br><br>CN101736188-GAUW-NI-22-23 | CONTACT NAME: ...<br>PHONE (A/C, No, Ext):<br>FAX (A/C, No):<br>E-MAIL ADDRESS: | |
| | INSURER(S) AFFORDING COVERAGE | NAIC # |
| | INSURER A : National Union Fire Insurance Co Of Pittsburgh | 19445 |
| INSURED<br>Philips North America LLC<br>222 Jacobs Street, 3rd Floor<br>Cambridge, MA 02141 | INSURER B : Safety National Casualty Corp. | 15105 |
| | INSURER C : | |
| | INSURER D : | |
| | INSURER E : | |
| | INSURER F : | |

**COVERAGES** **CERTIFICATE NUMBER:** NYC-011181363-12 **REVISION NUMBER:** 10

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

| INSR LTR | TYPE OF INSURANCE | ADDL INSD | SUBR WVD | POLICY NUMBER | POLICY EFF (MM/DD/YYYY) | POLICY EXP (MM/DD/YYYY) | LIMITS | | |
|---|---|---|---|---|---|---|---|---|---|
| A | COMMERCIAL GENERAL LIABILITY | | | 536-18-48 | 12/31/2022 | 12/31/2023 | EACH OCCURRENCE | $ | 2,000,000 |
| | [ ] CLAIMS-MADE [X] OCCUR | | | | | | DAMAGE TO RENTED PREMISES (Ea occurrence) | $ | 500,000 |
| | | | | | | | MED EXP (Any one person) | $ | 10,000 |
| | | | | | | | PERSONAL & ADV INJURY | $ | 2,000,000 |
| | GEN'L AGGREGATE LIMIT APPLIES PER: | | | | | | GENERAL AGGREGATE | $ | 5,000,000 |
| | [X] POLICY [ ] PRO-JECT [ ] LOC | | | | | | PRODUCTS - COMP/OP AGG | $ | 5,000,000 |
| | [ ] OTHER: | | | | | | | $ | |
| B | AUTOMOBILE LIABILITY | | | CA6675481 | 12/31/2022 | 12/31/2023 | COMBINED SINGLE LIMIT (Ea accident) | $ | 2,000,000 |
| | [X] ANY AUTO | | | | | | BODILY INJURY (Per person) | $ | |
| | [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS | | | | | | BODILY INJURY (Per accident) | $ | |
| | [ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY | | | | | | PROPERTY DAMAGE (Per accident) | $ | |
| | | | | | | | | $ | |
| A | [X] UMBRELLA LIAB [X] OCCUR | | | 10-736-193 | 12/31/2022 | 12/31/2023 | EACH OCCURRENCE | $ | 5,000,000 |
| | [ ] EXCESS LIAB [ ] CLAIMS-MADE | | | | | | AGGREGATE | $ | 5,000,000 |
| | [ ] DED [ ] RETENTION $ | | | | | | | $ | |
| B | WORKERS COMPENSATION AND EMPLOYERS' LIABILITY | | | LDS4047559 (AOS) | 12/31/2022 | 12/31/2023 | [X] PER STATUTE [ ] OTH-ER | | |
| B | ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBEREXCLUDED? (Mandatory in NH) Y/N [N] N/A | | | PS4047560 (WI) | 12/31/2022 | 12/31/2023 | E.L. EACH ACCIDENT | $ | 2,000,000 |
| | If yes, describe under DESCRIPTION OF OPERATIONS below | | | | | | E.L. DISEASE - EA EMPLOYEE | $ | 2,000,000 |
| | | | | | | | E.L. DISEASE - POLICY LIMIT | $ | 2,000,000 |
| A | CYBER LIABILITY | | | 03-932-59-76 | 12/31/2022 | 12/31/2023 | Occurrence Limit | | 10,000,000 |
| | | | | 'Subject to a policy deductible' | | | Aggregate Limit | | 10,000,000 |

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Additional Certificate Holder: Virginia Community College System Commonwealth of Virginia Virginia Community College System 147 Daleville Centre Drive Daleville, VA 24083.

Evidence of coverage.

**CERTIFICATE HOLDER**

Philips North America LLC
See above for the Complete Cert. Holder Name
222 Jacobs Street, 3rd Floor
Cambridge, MA 02141

**CANCELLATION**

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Marsh USA Inc.

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AGENCY CUSTOMER ID: CN101736188
LOC #: New York

ACORD®

# ADDITIONAL REMARKS SCHEDULE



| AGENCY | NAMED INSURED |
|---|---|
| Marsh USA, Inc. | Philips North America LLC<br>222 Jacobs Street, 3rd Floor<br>Cambridge, MA 02141 |
| POLICY NUMBER | |
| CARRIER / NAIC CODE | EFFECTIVE DATE: |

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Named Insured Includes:
370 West Trimble Road LLC
AllParts Medical, LLC
BioTelemetry, Inc.
BioTel Research, LLC
BioTelemetry Care Management, LLC
Telcare Medical Supply, LLC
Telcare, LLC
Braemar Manufacturing, LLC
Cardiac Monitoring Holding Company, LLC
LifeWatch Corp.
LifeWatch Services, Inc.
Cardiologs Technologies Inc.
CardioNet, LLC
BioTel INR, LLC
Geneva Healthcare, LLC
VirtualScopics, LLC
Blue Willow Systems LLC
Discus Holdings, LLC
Discus Dental, LLC
Discus International, LLC
Discus Dental Canada, LLC
Electrical Geodesics LLC
Cerebral Data Systems, Inc. (CDS)
Intact Vascular, Inc.
Philips CS Corporation (formerly "Vita Topco, Inc." and "Philips Capsule Corporation")
Capsule Technologies, Inc.
CapsuleTech, Inc.
Philips Healthcare Informatics, Inc.
Philips Image Guided Therapy Corporation
Cardioprolific Inc.
Crux Biomedical, LLC
Spectranetics LLC
Volcano Atheromed, Inc.
Philips Medical Systems (Cleveland), Inc.
Philips Medical Systems MR, Inc.
Philips DS North America LLC
Philips North America, LLC
Philips North America, LLC D/B/A Philips Healthcare
Philips Oral Healthcare, LLC
Philips RS North America Holding Corporation
Philips RS North America LLC
Respironics California, LLC
Respironics Colorado, Inc.
Respironics Logistics Services, LLC
Respironics Novametrix, LLC
Philips Semiconductors Inc.
Remote Diagnostics Technologies LLC


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AGENCY CUSTOMER ID: CN101736188
LOC #: New York

ACORD®

# ADDITIONAL REMARKS SCHEDULE



| AGENCY | NAMED INSURED |
|---|---|
| Marsh USA, Inc. | Philips North America LLC<br>222 Jacobs Street, 3rd Floor<br>Cambridge, MA 02141 |
| POLICY NUMBER | |
| CARRIER / NAIC CODE | EFFECTIVE DATE: |

## ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Respiratory Technologies, Inc.
Tomtec Corporation
TR Management Company, LLC
U.S. Philips Corporation
Vesper Medical, Inc.
VISICU, Inc.
VitalHealth Software Corp.
Wellcentive LLC (formerly "Wellcentive, Inc.")
Wellcentive QR, LLC
American Color & Chemical, L.L.C.
ATL Ultrasound, Inc.
Philips Ultrasound LLC (formerly "Philips Ultrasound, Inc.")
ATL International LLC
Philips Electronics North America Foundation
Philips Electronics Realty, LLC
Philips Medical Systems Export, Inc.
Philips MPEG Inc.
Philips Project Management, LLC


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# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

## PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 30185503

Application/License No. _____

*See attached list of principal names (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is *See attached list of principal addresses (Address of Applicant/Principal), as PRINCIPAL, and Western Surety Company (Surety Company), a corporation organized under the laws of the state of South Dakota (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 151 N Franklin Street Chicago, IL 60606 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 21, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 21st day of April, 20 23.

APPLICANT/PRINCIPAL

**See attached principal signature page

Authorized Representative

SURETY COMPANY

Western Surety Company

Surety Company's Representative

Kristin S. Bender, Attorney-in-fact

print name

Nevada Non-Resident Producer License No. 829075

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Jessica Tannotta

Witness April D. Perez

Countersigned by:

N/A

Nevada Resident Agent

# Western Surety Company

## POWER OF ATTORNEY APPOINTING INDIVIDUAL ATTORNEY-IN-FACT

**Know All Men By These Presents,** That WESTERN SURETY COMPANY, a South Dakota corporation, is a duly organized and existing corporation having its principal office in the City of Sioux Falls, and State of South Dakota, and that it does by virtue of the signature and seal herein affixed hereby make, constitute and appoint Kristin S. Bender

, Individually

of Morristown, New Jersey, its true and lawful Attorney(s)-in-Fact with full power and authority hereby conferred to sign, seal and execute for and on its behalf bonds, undertakings and other obligatory instruments of similar nature

**- In Unlimited Amounts -**

Surety Bond Number: 30185503
Principal: See attached list of principals
Obligee: State of Nevada and Nevada State Board of Pharmacy

and to bind it thereby as fully and to the same extent as if such instruments were signed by a duly authorized officer of the corporation and all the acts of said Attorney, pursuant to the authority hereby given, are hereby ratified and confirmed.

This Power of Attorney is made and executed pursuant to and by authority of the By-Law printed on the reverse hereof, duly adopted, as indicated, by the shareholders of the corporation.

**In Witness Whereof,** WESTERN SURETY COMPANY has caused these presents to be signed by its Vice President and its corporate seal to be hereto affixed on this 2nd day of February, 2021.

WESTERN SURETY COMPANY

Paul T. Bruflat

Paul T. Bruflat, Vice President

State of South Dakota }
County of Minnehaha } ss

On this 2nd day of February, 2021, before me personally came Paul T. Bruflat, to me known, who, being by me duly sworn, did depose and say: that he resides in the City of Sioux Falls, State of South Dakota; that he is the Vice President of WESTERN SURETY COMPANY described in and which executed the above instrument; that he knows the seal of said corporation; that the seal affixed to the said instrument is such corporate seal; that it was so affixed pursuant to authority given by the Board of Directors of said corporation and that he signed his name thereto pursuant to like authority, and acknowledges same to be the act and deed of said corporation.

My commission expires
March 2, 2026

M. BENT
NOTARY PUBLIC
SOUTH DAKOTA

M. Bent

M. Bent, Notary Public

**CERTIFICATE**

I, L. Nelson, Assistant Secretary of WESTERN SURETY COMPANY do hereby certify that the Power of Attorney hereinabove set forth is still in force, and further certify that the By-Law of the corporation printed on the reverse hereof is still in force. In testimony whereof I have hereunto subscribed my name and affixed the seal of the said corporation this 21 day of April, 2023.

WESTERN SURETY COMPANY

L. Nelson

L. Nelson, Assistant Secretary

Form F4280-2-2021

**Authorizing By-Law**

# ADOPTED BY THE SHAREHOLDERS OF WESTERN SURETY COMPANY

This Power of Attorney is made and executed pursuant to and by authority of the following By-Law duly adopted by the shareholders of the Company.

Section 7. All bonds, policies, undertakings, Powers of Attorney, or other obligations of the corporation shall be executed in the corporate name of the Company by the President, Secretary, and Assistant Secretary, Treasurer, or any Vice President, or by such other officers as the Board of Directors may authorize. The President, any Vice President, Secretary, any Assistant Secretary, or the Treasurer may appoint Attorneys in Fact or agents who shall have authority to issue bonds, policies, or undertakings in the name of the Company. The corporate seal is not necessary for the validity of any bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation. The signature of any such officer and the corporate seal may be printed by facsimile.

# WESTERN SURETY COMPANY
## Sioux Falls, South Dakota
## Statement of Net Admitted Assets and Liabilities
## December 31, 2021

### ASSETS

| | |
|---|---|
| Bonds | $ 1,940,298,870 |
| Stocks | 19,721,943 |
| Cash, cash equivalents, and short-term investments | 32,146,891 |
| Receivables for securities | 140,000 |
| Investment income due and accrued | 17,433,547 |
| Premiums and considerations | 54,366,110 |
| Amounts recoverable from reinsurers | 3,204,634 |
| Current federal and foreign income tax recoverable and interest thereon | - |
| Net deferred tax asset | 14,565,007 |
| Receivable from parent, subsidiaries, and affiliates | 14,891,869 |
| Other assets | 1,037 |
| Total Assets | $ 2,096,769,908 |

### LIABILITIES AND SURPLUS

| | |
|---|---|
| Losses | $ 214,859,103 |
| Loss adjustment expense | 48,667,258 |
| Commissions payable, contingent commissions and other similar charges | 10,885,216 |
| Other expenses (excluding taxes, license and fees | - |
| Taxes, License and fees (excluding federal and foreign income taxes) | 2,781,662 |
| Federal and foreign income taxes payable | 300,285 |
| Unearned premiums | 263,317,295 |
| Advance premiums | 6,618,279 |
| Ceded reinsurance premiums payable (net of ceding commissions) | 5,081,348 |
| Amounts withheld or retained by company for account of other | 10,237,011 |
| Provision for reinsurance | 6,261,560 |
| Payable to parent, subsidiaries and affiliates | 7,170 |
| Payable on security transactions | 35,226 |
| Other liabilities | 155,189 |
| Total Liabilities | $ 569,206,602 |

| | | |
|---|---|---|
| Surplus Account: | | |
| Common stock | $ 4,000,000 | |
| Gross paid in and contributed surplus | 286,896,195 | |
| Unassigned funds | 1,236,667,111 | |
| Surplus as regards policyholders | | $ 1,527,563,306 |
| Total Liabilities and Capital | | $ 2,096,769,908 |

I, Julie Lee, Assistant Vice President of Western Surety Company hereby certify that the above is an accurate representation of the financial statement of the Company dated December 31, 2021, as filed with the various Insurance Departments and is a true and correct statement of the condition of Western Surety Company as of that date.

WESTERN SURETY COMPANY

By Julie Lee
Assistant Vice President, External Reporting

Subscribed and sworn to me this 14th day of March, 2022.

My commission expires:

"OFFICIAL SEAL"
CHRISTOPHER LOPATOWSKI
Notary Public, State of Illinois
My Commission Expires 01/14/2024

By Christopher Lopatowski
Notary Public

**APPLICANT/PRINCIPALS:**

AllParts Medical, LLC, 400 Brick Church Park Drive, Nashville, TN 37207
Discus Dental, LLC, 1700 A South Baker Ave., Ontario, CA 91761
Philips Healthcare Informatics, Inc., 4430 Rosewood Drive, Suite 200, Pleasanton, CA 94588
Philips Healthcare, a division of Philips North America LLC, 22100 Bothell Everett Hwy, Bothell, WA 98021
Philips Healthcare, a division of Philips North America LLC, 222 Jacobs Street, Cambridge, MA 02141 Philips Ultrasound LLC, 22100 Bothell Everett Highway, Bothell, WA 98021
Philips Image Guided Therapy Corporation, 3721 Valley Center Drive, Suite 500, San Diego, CA 92130
Philips Image Guided Therapy Corporation, 2451 Mercantile Drive, Rancho Cordova, CA 95742
Respironics Logistics Services, LLC, 174 Tech Center Drive, Suite 200, Mt. Pleasant, PA 15666
Spectranetics LLC, 9965 Federal Drive, Colorado Springs, CO 80921
Visicu, Inc., 217 E. Redwood Street, Suite 1900, Baltimore, MD 21202

Paul Cavanaugh
Authorized Representative - [redacted] Paul Cavanaugh
Witness
Witness

Philips RS North America LLC, 1010 Murry Ridge Lane, Murrysville, PA 15668
Philips RS North America LLC, 174 Tech Center Drive, Suite 100, Mt. Pleasant, PA 15666

Authorized Representative - Stuart Cashman
Witness
Witness

Philips RS North America LLC LIMITED LIABILITY COMPANY SEAL 1984 DELAWARE

DISCUS DENTAL LLC LIMITED LIABILITY SEAL 2007 CALIFORNIA COMPANY

PHILIPS NORTH AMERICA LLC LIMITED LIABILITY SEAL 1987 DELAWARE COMPANY

PHILIPS ULTRASOUND LLC LIMITED LIABILITY SEAL 1973 WASHINGTON COMPANY

SPECTRANETICS LLC LIMITED LIABILITY SEAL 1988 DELAWARE COMPANY

IMAGE GUIDED THE SEAL 2000

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

**Section 1: Pharmacy/Wholesaler Information**

Name of Pharmacy/Wholesaler: Philips Image Guided Therapy Corporation

Pharmacy/Wholesaler License # (if applicable): Pending; current MDEG license #: MP01355

Physical Address: 2451 Mercantile Drive

City: Rancho Cordova State: CA Zip: 95742

Mailing Address (if different from physical address): Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover State: MA Zip: 01810

Telephone: 916-638-8008 Website: www.usa.philips.com/healthcare

Licensing Company Email: beth.c.rogers@philips.com

**Section 2: Personal Information**

First: Jonathan Middle: Bounchanh Last: Laosiri

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover State: MA Zip: 01810

Telephone: [redacted] Email: Jonathan.Laosiri@philips.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | X |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| California State University | | 08/90 - 05/94 | |
| **Address** | **City** | **State** | **Zip** |
| 6000 J Street | Sacramento | CA | 95819 |
| **Diploma/Degree obtained, if any** | | | |
| Bachelor of Science, Biology; Concentration: Medical Technology | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| 9/19/22 ABRAM ABRAHAN LINCOLN HS | | 09/84 - 06/87 | |
| **Address** | **City** | **State** | **Zip** |
| SAN FRANCISCO | SAN FRANCISCO | CA | 94122 |
| **Diploma/Degree obtained, if any** | | | |
| HS DIPLOMA | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 06/06 – Present | [redacted] Winding Oak Drive | Fair Oaks | CA | 95628 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Philips Image Guided Therapy Corporation | | 04/08 - Present | |
| **Business Address** | **City** | **State** | **Zip** |
| 2451 Mercantile Drive | Rancho Cordova | CA | 95742 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| 916-638-8008 | Manager, Rancho Cordova MFG Operation | 40 hours per week | |
| **Description of Duties** | | | |
| Responsible for overseeing/managing manufacturing operation onsite. | | | |

N/A

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

Continue on next page if additional space is needed.

N/A

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | X |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | X |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | X |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | X |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | X |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | X |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | X |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | X |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | X |

N/A

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # _____. **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| Reason/Charge | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| Name of Business/Industry/Entity | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

9/19/22
Date

I, Jonathan B. Laosiri, **certify that as the designated representative for**

Philips Image Guided Therapy Corporation,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. JU I am at least 21 years of age;
3. JU I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JU I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JU I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JU I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JU I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jonathan Laosiri
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/19/22
Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Jonathan Laosiri
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/26/22
~~9/19/22~~
Date @ 9/26/22

---

**Please have this section completed in the presence of a Notary Public.**

State of California, ss. County of Sacramento

I, JONATHAN LAOSIRI, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

9/26/22
**Date**

Subscribed and Sworn to before me this 26th day of Sept - 2022.

**Notary Public Signature**

DEBORAH KAYE GASKINS
COMM. # 2291621
NOTARY PUBLIC - CALIFORNIA
SACRAMENTO COUNTY
MY COMM. EXP. JUNE 6, 2023

**(Seal)**

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

## Attachment H

## Medical Devices, Equipment and Gases (MDEG) Administrator Form

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of MDEG Philips Image Guided Therapy Corporation MDEG License # (if applicable) MP01355

Physical Address 2451 Mercantile Drive

City Rancho Cordova State CA Zip 95742

Mailing Address (if different from physical address) Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City Andover State MA Zip 01810

Telephone 916-638-8008 Website www.usa.philips.com/healthcare

Licensing Company Email beth.c.rogers@philips.com

**Section 2: Personal Information**

First Jonathan Middle Bounchanh Last Laosiri

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City Andover State MA Zip 01810

Telephone [redacted] Email Jonathan.Laosiri@philips.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | X |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| California State University | | 08/90 - 05/94 | |
| **Address** | **City** | **State** | **Zip** |
| 6000 J Street | Sacramento | CA | 95819 |
| **Diploma/Degree obtained, if any** | | | |
| Bachelor of Science, Biology; Concentration: Medical Technology | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| ABRAHAN LINCOLN HS | | 09/84 - 06/87 | |
| **Address** | **City** | **State** | **Zip** |
| SAN FRANCISCO | SAN FRANCISCO | CA | 94122 |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| | [redacted]Winding Oak Drive | Fair Oaks | CA | 95628 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)**

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Philips Image Guided Therapy Corporation | | 04/08 - Present | |
| **Business Address** | **City** | **State** | **Zip** |
| 2451 Mercantile Drive | Rancho Cordova | CA | 95742 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| 916-638-8008 | Manager, Rancho Cordova MFG Operation | 40 hours per week | |
| **Description of Duties** | | | |
| Responsible for overseeing/managing manufacturing operation onsite. | | | |

N/A

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

Continue on next page if additional space is needed.

N/A

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | X |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state? | | X |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline. | | X |

N/A

**Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # _____. **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

9/19/22
Date

I, Jonathan B. Laosiri, **certify that as the MDEG Administrator for**

Philips Image Guided Therapy Corporation,

**that I (initial that you have read and meet the following requirements):**

1. JBL Have a high school diploma or its equivalent;
2. JBL Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JBL Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JBL Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Jonathan Laosiri
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/19/22
Date

| Board Use Only | Date Received: 5-11-23 |
|---|---|

# Philips Image Guided Therapy Corporate (Mercantile) Employee List

Andy Gerhardt
Angel Rodriguez
Arthur Rivera
Atila Forde
Catherine Leyva
Christie Nyman-Robbins
Claudia Rosas
Destinee Rogers
Felisha Rogers
Jamie Simpson
Jeffrey Barnhart
Jeffrey Deets
Jennifer Love
Jim Thao
Johnny Lee
Jose Lopez
Joseph Wolfe
Julie Riolo
Khoa Le
Madiha Jabeen
Melissa Farias
Michael Beckwith
Michael Henson
Nathan Graeff
Paul Larkin
Pete Garza
Phillip Donath
Soheil Chini
Steve Myers
Tara Skelton
William Hardin
Yosief Gebai

**2451 Mercantile Drive, Rancho Cordova -Employee on-site**

| First | Last | Manager |
|---|---|---|
| Jeffrey | Barnhart | Phil Donath |
| Brandon | Bigney | Julie Riolo |
| Soheil | Chini | Marlyne Enriquez |
| Phil | Donath | Steven Anastasio |
| Marlyne | Enriquez | Margaret Babaoye |
| Atila | Forde | Patrick Kozina |
| Nathan | Graeff | Marlyne Enriquez |
| Michael | Henson | Phil Donath |
| Madiha | Jabeen | Marlyne Enriquez |
| Paul | Larkin | Phil Donath |
| Khoa | Le | Julie Riolo |
| Johnny | Lee | Jonathan Laosiri |
| Catherine | Leyva | Kara Carter |
| Jose | Lopez | Phil Donath |
| Steven | Myers | Phil Donath |
| Christie | Nyman-Robbins | Ashley Krieger |
| Julie | Riolo | Jonathan Laosiri |
| Angel | Rodriguez | Phil Donath |
| Claudia | Rosas | Phil Donath |
| Jamie | Simpson | Phil Donath |
| Jim | Thao | Phil Donath |
| Glainy | Villabrille | Phil Donath |
| Rommel | Viviezca | Phil Donath |
| Joseph | Wolfe | Julie Riolo |
| Andy | Gerhardt | Jonathan Laosiri |

# 4S

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

### Non-Refundable $1,000 Fee

Rev (05/12/2022)

| Where is the facility located? | | ☐ Nevada ☑ Out-of-State |
|---|---|---|
| **Type of Application (check applicable box)** | | **Wholesaler Business Type (check applicable box)** |
| ☑ New Wholesaler<br>☐ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>current MDEG license WH #: MP01128 | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: Philips Ultrasound LLC

Physical Address: 22100 Bothell Everett Highway

City: Bothell State: WA Zip: 98021

Mailing Address (if different from physical address): Phillips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover State: MA Zip: 01810

Telephone: 425-487-7900 Website: www.usa.philips.com/healthcare

Name of Designated Representative (DR): Matthew L. Holttum

Licensing Company Email: beth.c.rogers@philips.com DR Email: matt.holttum@philips.com

| Entities the Wholesaler will Serve (✓ all applicable) | Products to be Handled or Wholesaled (✓ all applicable) | Type of Wholesaling (✓ all applicable) |
|---|---|---|
| ☐ Pharmacies | ☐ Dangerous Drugs | ☑ Manufacturer |
| ☑ Practitioners | ☐ Controlled Substances | ☐ Repacker |
| ☑ Hospitals | ☑ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ☐ Wholesalers | ☐ Others: | ☐ Warehouse |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ☑ Others: Clinics and Distributors. | | ☐ Others: |

| Section 2: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | X |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | X |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | X |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | X |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | X |

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: N/A - No pharmaceuticals products are handled or sold. See Attachment A.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

N/A

**Section 4: Publicly Traded Corporation**

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: Washington

Parent Company (if any): ATL Ultrasound, Inc.

Corporation/Organization Name: Philips Ultrasound LLC

Mailing Address: Phillips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover State: MA Zip: 01810

Telephone: 978-659-4884 Email: beth.c.rogers@philips.com

Contact Person Name: Beth C. Rogers

N/A

**Section 6: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A

**Section 7: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | X |
| 1. Copy of Certification<br>N/A 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | X | |
| 1. Copy of FDA registration See Attachment B<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment C | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** See Attachment D | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** N/A | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** See Attachment D | | ✓ | | |
| • **List of all partners and their percent ownership.** N/A | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment E | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment F | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - Wholly-owned by parent company, ATL Ultrasound, Inc. | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** N/A | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) N/A | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment D | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment G | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ See Attachment H | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). See Attachment I | ✓ | ✓ | ✓ | ✓ |
| N/A **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Philips Ultrasound LLC

Facility Name

Matthew L. Holttum

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

11/30/22

Date

| Board Use Only | Date Received: 7/3/23 | Amount: 1000 - CK - 913 |
|---|---|---|

## Attachment A

## Nature of Business

Philips Ultrasound LLC (Philips) is a manufacturer of prescription and non-prescription medical devices. Philips' Bothell, WA location manufactures Ultrasound scanning products.

The Bothell location sells and ships its products to customers (clinics, distributors, hospitals, physicians, and veterinarians). All products manufactured at the Bothell location are shipped to customers by Philips' Bothell, WA location.

Provided below are the locations that manufacture and distribute:

**Manufacturing Location:**

Philips Ultrasound LLC
22100 Bothell Everett Hwy
Bothell, WA 98021

**Distributing Location:**

Philips Ultrasound LLC
22100 Bothell Everett Hwy
Bothell, WA 98021

FDA

FDA Home[3] Medical Devices[4] Databases[5]

## Establishment Registration & Device Listing

New Search

Back To Search Results

**Establishment:**
Philips Ultrasound LLC
**Business Trade Names:**
(1) Philips (2) Philips Healthcare (3) Philips Medical Systems

22100 Bothell Everett Hwy
BOTHELL, WA 98021
**Registration Number:** 3019216
**FEI Number*:** 3019216
**Status:** Active
**Initial Distributor/Importer:** Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
**Date Of Registration Status:** 2023

Verified 7.5.23

**Owner/Operator:**

Philips Medical Systems International BV[6]
Veenpluis 6
Best, NL 5684PC
**Owner/Operator Number:** 1217116[7]

**Official Correspondent:**
Thuy Nguyen
Philips
22100 Bothell Everett Highway
Bothell, WA 98021
**Phone:** 612-4012475

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1217116&OwnerOperator
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1217116&OwnerOperator

Page Last Updated: 07/03/2023

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

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U.S. Department of **Health & Human Services**

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5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases

6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?
start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1217116&OwnerOperator

7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?
start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1217116&OwnerOperator

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[3] Medical Devices[4] Databases[5]

## Establishment Registration & Device Listing

New Search Back To Search Results

**Establishment:**
Philips North America LLC
**Business Trade Names:**
(1) Philips (2) Philips Healthcare (3) Philips Medical Systems (4) Philips Ultrasound & Monitoring

3000 Minuteman Rd
ANDOVER, MA 01810
**Registration Number:** 1218950
**FEI Number*:** 1218950
**Status:** Active
**Initial Distributor/Importer:** Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
**Date Of Registration Status:** 2023

**Owner/Operator:**

Philips Medical Systems International BV[6]
Veenpluis 6
Best, NL 5684PC
**Owner/Operator Number:** 1217116[7]

**Official Correspondent:**
Karen Smith
PHILIPS
222 Jacobs Street
Cambridge, MA 02141
**Phone:** 617-6681011

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=@Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1217116&OwnerOperator
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=@Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1217116&OwnerOperator

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U.S. Department of Health & Human Services

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4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases

6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?
start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1217116&OwnerOperator
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?
start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1217116&OwnerOperator

**Attachment D**

**LLC Information**

Philips Ultrasound LLC

**Philips Ultrasound LLC is wholly-owned by its parent company, ATL Ultrasound, Inc. No individuals hold any ownership interest in the company.**

**LLC Officers:**

**Jeff Cohen**
*President/General Manager*

**Leonardus Ammerlaan**
*Vice President and Treasurer*

**Ling Liu**
*Vice President*

**Joseph E. Innamorati**
*Vice President and Secretary*

**Paul Cavanaugh**
*Vice President*

**Michael Lapin**
*Assistant Secretary*

**Irma I. Gomez**
*Assistant Secretary*

**Directors:**

Joseph E. Innamorati
Ling Liu

**Facility Manager:**

**Matthew L. Holttum**
*Director, System Operations*

Enclosed please find a list all site employees.

UNITED STATES OF AMERICA

# The State of Washington

## Secretary of State

**I, STEVE R. HOBBS**, Secretary of State of the State of Washington and custodian of its seal, hereby issue this

**CERTIFICATE OF EXISTENCE**

**OF**

**PHILIPS ULTRASOUND LLC**

**I CERTIFY** that the records on file in this office show that the above named entity was formed under the laws of the State of Washington and that its public organic record was filed in Washington and became effective on 03/14/1973.

**I FURTHER CERTIFY** that the entity's duration is Perpetual, and that as of the date of this certificate, the records of the Secretary of State do not reflect that this entity has been dissolved.

**I FURTHER CERTIFY** that all fees, interest, and penalties owed and collected through the Secretary of State have been paid.

**I FURTHER CERTIFY** that the most recent annual report has been delivered to the Secretary of State for filing and that proceedings for administrative dissolution are not pending.

Issued Date: 03/14/2023
UBI Number: 600 094 395

Given under my hand and the Seal of the State of Washington at Olympia, the State Capital

Steve R. Hobbs, Secretary of State

Date Issued: 03/14/2023

## Attachment G

## Regarding the Resident State License

Please note that the resident state licensing agency, the Washington Board of Pharmacy (Board), does not license prescription device manufacturers and distributors. Enclosed please find correspondence from the Board confirming that a license is not required.

## Garrison, Rachael E.

**From:** Beebe, Doreen (DOH) <Doreen.Beebe@DOH.WA.GOV>
**Sent:** Wednesday, April 09, 2014 2:26 PM
**To:** Rachael Garrison
**Subject:** RE: Prescription Device Question

The pharmacy commission does not issue a credential for the wholesale or distribution of devises so long as no pharmaceuticals are included in the distribution. Doreen

*Always Working for a Safer and Healthier Washington.*

**Doreen E. Beebe | Program Manager**
Washington State Pharmacy Quality Assurance Commission

PO Box 47852
Olympia WA 98504-7852
P: 360.236.4834 | F: 360.236.4626

Physical Address:
111 Israel Road SE
Tumwater WA 98501

Pharmacy Quality Assurance Commission
Join or Leave the PQAC Newsletter Distribution List

**From:** Rachael Garrison [mailto:garrison@PorzioLS.com]
**Sent:** Wednesday, April 09, 2014 11:12 AM
**To:** Beebe, Doreen (DOH)
**Subject:** Prescription Device Question

Dear Ms. Beebe,

It is my understanding that your office does not license in-state and out-of-state distributors and manufacturers of prescription devices. Kindly confirm if my understanding is correct.

Sincerely,

Rachael

Rachael Garrison
Regulatory Analyst

Porzio Life Sciences, LLC
100 Southgate Parkway
P.O. Box 1997
Morristown, NJ 07962-1997

garrison@PorzioLS.com

973 889-4333 (direct)
973 538-5146 (fax)

www.porziolifesciences.com

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Health

Visit our COVID-19 page for the latest updates, vaccine information, testing locations and data dashboard.



# Pharmaceutical Firms

## Pharmacy Firm Licensing

### Apply for a License

Applications and forms >

### Fee schedule

Licensing fees >

### Licensing Requirements

Controlled Substance Researcher >

Health Care Entity >

Itinerant Vendor or Peddler >

Legend Drug Sample Distributor >

Other Controlled Substance >

Pharmaceutical Wholesaler and Manufacturer ⌄

Licensing Requirements ⌄

- Chapter 18.64 RCW
- Chapter 246-879 WAC
- Chapter 246-889 WAC

Note: the commission will no longer license entities exclusively engaged in third-party logistics, as defined in 21 U.S.C. § 360eee(22). While the commission will not license third-party logistics providers (3PLs), 3PLs are federally required to report annually to the FDA.

A wholesaler that sell legend drugs and nonprescription, or nonprescription drugs in this state must be licensed as a wholesale distributor. A "wholesale distributor" means anyone engaged in wholesale distribution of drugs, including but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers;

warehouses; including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions. Types of practice licensed in this category:

Wholesaler Application:

- Full-line wholesaler (prescription and nonprescription drugs)
- Full-line wholesaler with controlled substances
- Over-the-Counter Drug Wholesaler
- Export Wholesaler
- Non-profit Wholesaler
- Reverse distributor
- Out-of-State Manufacturer
- Out-of-State Virtual Manufacturer
- In and Out-of-State Virtual Wholesalers
- 503B Outsourcing Facilities
- Retail pharmacies engaging in wholesale distribution

Manufacturer Applications – apply to locations in Washington state that manufacturer pharmaceuticals or engage in virtual manufacturer practice in-state only

In-state wholesalers and manufacturers are inspected before a license is issued and periodically to ensure compliance with laws and rules.

Non-resident manufacturers that sell or distribute legend drugs and nonprescription, or nonprescription drugs in this state must be licensed as a Washington pharmaceutical wholesaler and as a legend drug sample distributor if sample drugs are distributed.

No license is required for the wholesale distribution of medical devices so long as no pharmaceuticals are involved.

## State license verification

Applicants must list all states where they do or did hold credentials. This list must also include when the applicant has applied for a credential, even if a credential was not granted. The jurisdiction where the applicant is or was credentialed must complete and submit the submit the verification form (PDF). The jurisdiction must send the completed form directly to the department.

## Background questions

Applicant must answer background questions related to the owners, partners, managers, etc. If there is a positive answer to the professional liability questions the applicant must send an explanation of the nature of the case, data and summary of care given, copies of the original complaint, and the settlement or final disposition. If the case is pending, applicant must indicate status.

## Additional information/documents required

Out-of-state wholesalers must provide:

- Copy of resident state license;
- Copy of most recent inspection by the licensing authority or an explanation why it cannot be provided; and
- If applicable, a copy of the facility's federal Drug Enforcement Administration registration.

## Process for approving/denying applications

Credentialing staff members review the application and supporting documents to make an initial determination on eligibility. The recommendation is based upon the requirements outlined in Chapter 18.64 RCW, and Chapter 246-879 WAC. Credentialing supervisors approve routine applications that don't have positive answers to personal data questions, have questionable verifying documents or are otherwise "red flag" applications. "Red flag" applications are forwarded to the exception application process for determination by the appropriate disciplinary authority. An applicant will be formally notified of a denial and has the opportunity for a hearing to appeal the decision.

## Renewal requirements

Pharmaceutical wholesaler and manufacturer licenses are renewed annually on or before September 30 and may be renewed within 90 days of the expiration date.

A courtesy renewal notice will be mailed to licensee's address of record. Renewals mailed to the department must be postmarked on or before the expiration date to avoid having the license expire and accrue a late penalty.

## Location or ownership changes

A change of location to a different address requires a new application and payment of original licensing fees, including CSA.

A change in the business structure or organizational structure such as a change from sole proprietorship to a corporation or a change of more than 50 percent of ownership in a corporation requires a new application and original licensing fees, including CSA.

In-state wholesalers must pass an inspection before a new location or change of ownership license is issued.

## Third Party Logistic Providers -- 3PLs

The Washington Pharmacy Quality Assurance Commission discussed third-party logistic (3PL) providers at its March 2018 business meeting. The commission decided it will no longer license entities exclusively engaged in third-party logistics, as defined in 21 U.S.C. § 360eee(22). While the commission will not license third-party logistics providers (3PLs), 3PLs are federally required to report annually to the FDA.

Poison Distributor or Poison Manufacturer ›

Precursor Drug Distributor Permit ›

Shopkeeper ›

Sodium Pentobarbital Registration Requirements ›

Washington Department of Fish and Wildlife Chemical Capture ›

ACORD®

# CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
01/03/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

**PRODUCER**
Marsh USA, Inc.
1166 Avenue of the Americas
New York, NY 10036

CN101736188-GAUW-NI-22-23

**CONTACT NAME:**
**PHONE (A/C, No, Ext):** **FAX (A/C, No):**
**E-MAIL ADDRESS:**

| INSURER(S) AFFORDING COVERAGE | NAIC # |
|---|---|
| INSURER A : National Union Fire Insurance Co Of Pittsburgh | 19445 |
| INSURER B : Safety National Casualty Corp. | 15105 |
| INSURER C : | |
| INSURER D : | |
| INSURER E : | |
| INSURER F : | |

**INSURED**
Philips North America LLC
222 Jacobs Street, 3rd Floor
Cambridge, MA 02141

**COVERAGES** **CERTIFICATE NUMBER:** NYC-011181363-12 **REVISION NUMBER:** 10

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

| INSR LTR | TYPE OF INSURANCE | ADDL INSD | SUBR WVD | POLICY NUMBER | POLICY EFF (MM/DD/YYYY) | POLICY EXP (MM/DD/YYYY) | LIMITS | | |
|---|---|---|---|---|---|---|---|---|---|
| A | COMMERCIAL GENERAL LIABILITY | | | 536-18-48 | 12/31/2022 | 12/31/2023 | EACH OCCURRENCE | $ | 2,000,000 |
| | [ ] CLAIMS-MADE [X] OCCUR | | | | | | DAMAGE TO RENTED PREMISES (Ea occurrence) | $ | 500,000 |
| | | | | | | | MED EXP (Any one person) | $ | 10,000 |
| | | | | | | | PERSONAL & ADV INJURY | $ | 2,000,000 |
| | GEN'L AGGREGATE LIMIT APPLIES PER: | | | | | | GENERAL AGGREGATE | $ | 5,000,000 |
| | [X] POLICY [ ] PRO-JECT [ ] LOC | | | | | | PRODUCTS - COMP/OP AGG | $ | 5,000,000 |
| | OTHER: | | | | | | | $ | |
| B | AUTOMOBILE LIABILITY | | | CA6675481 | 12/31/2022 | 12/31/2023 | COMBINED SINGLE LIMIT (Ea accident) | $ | 2,000,000 |
| | [X] ANY AUTO | | | | | | BODILY INJURY (Per person) | $ | |
| | [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS | | | | | | BODILY INJURY (Per accident) | $ | |
| | [ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY | | | | | | PROPERTY DAMAGE (Per accident) | $ | |
| | | | | | | | | $ | |
| A | [X] UMBRELLA LIAB [X] OCCUR | | | 10-736-193 | 12/31/2022 | 12/31/2023 | EACH OCCURRENCE | $ | 5,000,000 |
| | [ ] EXCESS LIAB [ ] CLAIMS-MADE | | | | | | AGGREGATE | $ | 5,000,000 |
| | [ ] DED [ ] RETENTION $ | | | | | | | $ | |
| B | WORKERS COMPENSATION AND EMPLOYERS' LIABILITY | | | LDS4047559 (AOS) | 12/31/2022 | 12/31/2023 | [X] PER STATUTE [ ] OTH-ER | | |
| B | ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [N] N/A (Mandatory in NH) | | | PS4047560 (WI) | 12/31/2022 | 12/31/2023 | E.L. EACH ACCIDENT | $ | 2,000,000 |
| | If yes, describe under DESCRIPTION OF OPERATIONS below | | | | | | E.L. DISEASE - EA EMPLOYEE | $ | 2,000,000 |
| | | | | | | | E.L. DISEASE - POLICY LIMIT | $ | 2,000,000 |
| A | CYBER LIABILITY | | | 03-932-59-76 | 12/31/2022 | 12/31/2023 | Occurrence Limit | | 10,000,000 |
| | | | | 'Subject to a policy deductible' | | | Aggregate Limit | | 10,000,000 |

**DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)**
Additional Certificate Holder: Virginia Community College System Commonwealth of Virginia Virginia Community College System 147 Daleville Centre Drive Daleville, VA 24083.

Evidence of coverage.

**CERTIFICATE HOLDER**

Philips North America LLC
See above for the Complete Cert. Holder Name
222 Jacobs Street, 3rd Floor
Cambridge, MA 02141

**CANCELLATION**

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Marsh USA Inc.

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AGENCY CUSTOMER ID: CN101736188
LOC #: New York

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# ADDITIONAL REMARKS SCHEDULE



| AGENCY | NAMED INSURED |
|---|---|
| Marsh USA, Inc. | Philips North America LLC<br>222 Jacobs Street, 3rd Floor<br>Cambridge, MA 02141 |
| POLICY NUMBER | |
| CARRIER / NAIC CODE | EFFECTIVE DATE: |

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Named Insured Includes:
370 West Trimble Road LLC
AllParts Medical, LLC
BioTelemetry, Inc.
BioTel Research, LLC
BioTelemetry Care Management, LLC
Telcare Medical Supply, LLC
Telcare, LLC
Braemar Manufacturing, LLC
Cardiac Monitoring Holding Company, LLC
LifeWatch Corp.
LifeWatch Services, Inc.
Cardiologs Technologies Inc.
CardioNet, LLC
BioTel INR, LLC
Geneva Healthcare, LLC
VirtualScopics, LLC
Blue Willow Systems LLC
Discus Holdings, LLC
Discus Dental, LLC
Discus International, LLC
Discus Dental Canada, LLC
Electrical Geodesics LLC
Cerebral Data Systems, Inc. (CDS)
Intact Vascular, Inc.
Philips CS Corporation (formerly "Vita Topco, Inc." and "Philips Capsule Corporation")
Capsule Technologies, Inc.
CapsuleTech, Inc.
Philips Healthcare Informatics, Inc.
Philips Image Guided Therapy Corporation
Cardioprolific Inc.
Crux Biomedical, LLC
Spectranetics LLC
Volcano Atheromed, Inc.
Philips Medical Systems (Cleveland), Inc.
Philips Medical Systems MR, Inc.
Philips DS North America LLC
Philips North America, LLC
Philips North America, LLC D/B/A Philips Healthcare
Philips Oral Healthcare, LLC
Philips RS North America Holding Corporation
Philips RS North America LLC
Respironics California, LLC
Respironics Colorado, Inc.
Respironics Logistics Services, LLC
Respironics Novametrix, LLC
Philips Semiconductors Inc.
Remote Diagnostics Technologies LLC


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AGENCY CUSTOMER ID: CN101736188
LOC #: New York

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# ADDITIONAL REMARKS SCHEDULE



| AGENCY | NAMED INSURED |
|---|---|
| Marsh USA, Inc. | Philips North America LLC<br>222 Jacobs Street, 3rd Floor<br>Cambridge, MA 02141 |
| POLICY NUMBER | |
| CARRIER / NAIC CODE | EFFECTIVE DATE: |

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Respiratory Technologies, Inc.
Tomtec Corporation
TR Management Company, LLC
U.S. Philips Corporation
Vesper Medical, Inc.
VISICU, Inc.
VitalHealth Software Corp.
Wellcentive LLC (formerly "Wellcentive, Inc.")
Wellcentive QR, LLC
American Color & Chemical, L.L.C.
ATL Ultrasound, Inc.
Philips Ultrasound LLC (formerly "Philips Ultrasound, Inc.")
ATL International LLC
Philips Electronics North America Foundation
Philips Electronics Realty, LLC
Philips Medical Systems Export, Inc.
Philips MPEG Inc.
Philips Project Management, LLC


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# Western Surety Company

## POWER OF ATTORNEY APPOINTING INDIVIDUAL ATTORNEY-IN-FACT

**Know All Men By These Presents,** That WESTERN SURETY COMPANY, a South Dakota corporation, is a duly organized and existing corporation having its principal office in the City of Sioux Falls, and State of South Dakota, and that it does by virtue of the signature and seal herein affixed hereby make, constitute and appoint Kristin S. Bender

, Individually

of Morristown, New Jersey, its true and lawful Attorney(s)-in-Fact with full power and authority hereby conferred to sign, seal and execute for and on its behalf bonds, undertakings and other obligatory instruments of similar nature

**- In Unlimited Amounts -**

Surety Bond Number: 30185503
Principal: See attached list of principals
Obligee: State of Nevada and Nevada State Board of Pharmacy

and to bind it thereby as fully and to the same extent as if such instruments were signed by a duly authorized officer of the corporation and all the acts of said Attorney, pursuant to the authority hereby given, are hereby ratified and confirmed.

This Power of Attorney is made and executed pursuant to and by authority of the By-Law printed on the reverse hereof, duly adopted, as indicated, by the shareholders of the corporation.

**In Witness Whereof,** WESTERN SURETY COMPANY has caused these presents to be signed by its Vice President and its corporate seal to be hereto affixed on this 2nd day of February, 2021.

WESTERN SURETY COMPANY

Paul T. Bruflat

Paul T Bruflat, Vice President

State of South Dakota }
County of Minnehaha } ss

On this 2nd day of February, 2021, before me personally came Paul T. Bruflat, to me known, who, being by me duly sworn, did depose and say: that he resides in the City of Sioux Falls, State of South Dakota; that he is the Vice President of WESTERN SURETY COMPANY described in and which executed the above instrument; that he knows the seal of said corporation; that the seal affixed to the said instrument is such corporate seal; that it was so affixed pursuant to authority given by the Board of Directors of said corporation and that he signed his name thereto pursuant to like authority, and acknowledges same to be the act and deed of said corporation.

My commission expires
March 2, 2026

M. BENT
NOTARY PUBLIC
SOUTH DAKOTA

M. Bent

M. Bent, Notary Public

### CERTIFICATE

I, L. Nelson, Assistant Secretary of WESTERN SURETY COMPANY do hereby certify that the Power of Attorney hereinabove set forth is still in force, and further certify that the By-Law of the corporation printed on the reverse hereof is still in force. In testimony whereof I have hereunto subscribed my name and affixed the seal of the said corporation this 21 day of April, 2023.

WESTERN SURETY COMPANY

L. Nelson

L. Nelson, Assistant Secretary

Form F4280-2-2021

**Authorizing By-Law**

## ADOPTED BY THE SHAREHOLDERS OF WESTERN SURETY COMPANY

This Power of Attorney is made and executed pursuant to and by authority of the following By-Law duly adopted by the shareholders of the Company.

Section 7. All bonds, policies, undertakings, Powers of Attorney, or other obligations of the corporation shall be executed in the corporate name of the Company by the President, Secretary, and Assistant Secretary, Treasurer, or any Vice President, or by such other officers as the Board of Directors may authorize. The President, any Vice President, Secretary, any Assistant Secretary, or the Treasurer may appoint Attorneys in Fact or agents who shall have authority to issue bonds, policies, or undertakings in the name of the Company. The corporate seal is not necessary for the validity of any bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation. The signature of any such officer and the corporate seal may be printed by facsimile.

# WESTERN SURETY COMPANY
## Sioux Falls, South Dakota
## Statement of Net Admitted Assets and Liabilities
## December 31, 2021

### ASSETS

| | |
|---|---|
| Bonds | $ 1,940,298,870 |
| Stocks | 19,721,943 |
| Cash, cash equivalents, and short-term investments | 32,146,891 |
| Receivables for securities | 140,000 |
| Investment income due and accrued | 17,433,547 |
| Premiums and considerations | 54,366,110 |
| Amounts recoverable from reinsurers | 3,204,634 |
| Current federal and foreign income tax recoverable and interest thereon | - |
| Net deferred tax asset | 14,565,007 |
| Receivable from parent, subsidiaries, and affiliates | 14,891,869 |
| Other assets | 1,037 |
| Total Assets | $ 2,096,769,908 |

### LIABILITIES AND SURPLUS

| | |
|---|---|
| Losses | $ 214,859,103 |
| Loss adjustment expense | 48,667,258 |
| Commissions payable, contingent commissions and other similar charges | 10,885,216 |
| Other expenses (excluding taxes, license and fees | - |
| Taxes, License and fees (excluding federal and foreign income taxes) | 2,781,662 |
| Federal and foreign income taxes payable | 300,285 |
| Unearned premiums | 263,317,295 |
| Advance premiums | 6,618,279 |
| Ceded reinsurance premiums payable (net of ceding commissions) | 5,081,348 |
| Amounts withheld or retained by company for account of other | 10,237,011 |
| Provision for reinsurance | 6,261,560 |
| Payable to parent, subsidiaries and affiliates | 7,170 |
| Payable on security transactions | 35,226 |
| Other liabilities | 155,189 |
| Total Liabilities | $ 569,206,602 |

| | | |
|---|---|---|
| Surplus Account: | | |
| Common stock | $ 4,000,000 | |
| Gross paid in and contributed surplus | 286,896,195 | |
| Unassigned funds | 1,236,667,111 | |
| Surplus as regards policyholders | | $ 1,527,563,306 |
| Total Liabilities and Capital | | $ 2,096,769,908 |

I, Julie Lee, Assistant Vice President of Western Surety Company hereby certify that the above is an accurate representation of the financial statement of the Company dated December 31, 2021, as filed with the various Insurance Departments and is a true and correct statement of the condition of Western Surety Company as of that date.

WESTERN SURETY COMPANY

By Julie Lee
Assistant Vice President, External Reporting

Subscribed and sworn to me this 14th day of March, 2022.

My commission expires:

"OFFICIAL SEAL"
CHRISTOPHER LOPATOWSKI
Notary Public, State of Illinois
My Commission Expires 01/14/2024

By Christopher Lopatowski
Notary Public

# NEVADA STATE BOARD OF PHARMACY

**985 Damonte Ranch Pkwy Suite 206**
**Reno, NV 89521**
**(775) 850-1440**
**Fax: (775) 850-1444**

## PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 30185503

Application/License No. _____

*See attached list of principal names (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is *See attached list of principal addresses (Address of Applicant/Principal), as PRINCIPAL, and Western Surety Company (Surety Company), a corporation organized under the laws of the state of South Dakota (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 151 N Franklin Street Chicago, IL 60606 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 21, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 21st day of April, 20 23.

APPLICANT/PRINCIPAL

**See attached principal signature page

Authorized Representative

SURETY COMPANY

Western Surety Company

Surety Company's Representative

Kristin S. Bender, Attorney-in-fact

print name

Nevada Non-Resident Producer License No. 829075

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Jessica Iannotta

Witness April D. Perez

Countersigned by:

N/A

Nevada Resident Agent

**APPLICANT/PRINCIPALS:**

AllParts Medical, LLC, 400 Brick Church Park Drive, Nashville, TN 37207
Discus Dental, LLC, 1700 A South Baker Ave., Ontario, CA 91761
Philips Healthcare Informatics, Inc., 4430 Rosewood Drive, Suite 200, Pleasanton, CA 94588
Philips Healthcare, a division of Philips North America LLC, 22100 Bothell Everett Hwy, Bothell, WA 98021
Philips Healthcare, a division of Philips North America LLC, 222 Jacobs Street, Cambridge, MA 02141 Philips Ultrasound LLC, 22100 Bothell Everett Highway, Bothell, WA 98021
Philips Image Guided Therapy Corporation, 3721 Valley Center Drive, Suite 500, San Diego, CA 92130
Philips Image Guided Therapy Corporation, 2451 Mercantile Drive, Rancho Cordova, CA 95742
Respironics Logistics Services, LLC, 174 Tech Center Drive, Suite 200, Mt. Pleasant, PA 15666
Spectranetics LLC, 9965 Federal Drive, Colorado Springs, CO 80921
Visicu, Inc., 217 E. Redwood Street, Suite 1900, Baltimore, MD 21202

Authorized Representative - Paul Cavanaugh

Witness

Witness

Philips RS North America LLC, 1010 Murry Ridge Lane, Murrysville, PA 15668
Philips RS North America LLC, 174 Tech Center Drive, Suite 100, Mt. Pleasant, PA 15666

Authorized Representative - Stuart Cashman

Witness

Witness

Philips RS North America LLC LIMITED LIABILITY COMPANY SEAL 1984 DELAWARE

DISCUS DENTAL LLC LIMITED LIABILITY COMPANY SEAL 2007 CALIFORNIA

PHILIPS NORTH AMERICA LLC LIMITED LIABILITY COMPANY SEAL 1987 DELAWARE

PHILIPS ULTRASOUND LLC LIMITED LIABILITY COMPANY SEAL 1973 WASHINGTON

SPECTRANETICS LLC LIMITED LIABILITY COMPANY SEAL 1988 DELAWARE

IMAGE GUIDED THERAPY CORPORATION SEAL 2000

## Attachment H

## Medical Devices, Equipment and Gases (MDEG) Administrator Form

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of MDEG: Philips Ultrasound LLC — MDEG License # (if applicable): MP01128

Physical Address: 22100 Bothell Everett Highway

City: Bothell — State: WA — Zip: 98021

Mailing Address (if different from physical address): Philips Healthcare, Attn: Beth Rogers, 3000 Minuteman Road

City: Andover — State: MA — Zip: 01810

Telephone: 425-487-7900 — Website: www.usa.philips.com/healthcare

Licensing Company Email: beth.c.rogers@philips.com

**Section 2: Personal Information**

First: Matthew — Middle: Lee — Last: Holttum

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☑ M ☐ F ☐ X

Mailing Address: Philips Healthcare, Attn: Beth Rogers, 3000 Minuteman Road

City: Andover — State: MA — Zip: 01810

Telephone: [redacted] — Email: matt.holttum@philips.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| University of Washington | | 08/85 - 05/88 | |
| **Address** | **City** | **State** | **Zip** |
| 1410 NE Campus Parkway | Seattle | WA | 98195 |
| **Diploma/Degree obtained, if any** | | | |
| Bachelor of Arts (BA) - Business & Bachelor of Science (BS) - Psychology | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Greys Harbor CC | | 9/83 - 8/85 | |
| **Address** | **City** | **State** | **Zip** |
| 1620 Edward P. Smith Dr. | Aberdeen | WA | 98520 |
| **Diploma/Degree obtained, if any** | | | |
| Associate of Science (AS) | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Aberdeen High School | | 9/80 - 6/83 | |
| **Address** | **City** | **State** | **Zip** |
| 500 N. G St. | Aberdeen | WA | 98520 |
| **Diploma/Degree obtained, if any** | | | |
| High School Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 7/96 - DATE | [redacted] 143rd PL SW | Lynnwood | WA | 98087 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)**

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Philips Ultrasound LLC (f/k/a Philips Ultrasound, Inc.) | | 07/91 - Present | |
| **Business Address** | **City** | **State** | **Zip** |
| 22100 Bothell Everett Highway | Bothell | WA | 98021 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| 425-487-7836 | Director, System Operations | 40 hours per week | |
| **Description of Duties** | | | |
| Responsible for production lines and factory operations. | | | |

N/A

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

Continue on next page if additional space is needed.

N/A

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state? | | ✓ |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline. | | ✓ |

N/A

**Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| | | | | |
| Reason/Charge | | | | |
| | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| | | | | |
| Name of Business/Industry/Entity | | | | |
| | | | | |

**Provide explanation below:**

Mark L Ulm
Original Signature (electronic, copies or stamps not accepted)

11/30/22
Date

I, Matthew L. Holttum, **certify that as the MDEG Administrator for**

Philips Ultrasound LLC,

**that I (initial that you have read and meet the following requirements):**

1. MH Have a high school diploma or its equivalent;
2. MH Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MH Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MH Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Matthew Holttum
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/30/22
Date

| Board Use Only | Date Received: 1-3-23 |
|---|---|

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

**Section 1: Pharmacy/Wholesaler Information**

Name of Pharmacy/Wholesaler: Philips Ultrasound LLC

Pharmacy/Wholesaler License # (if applicable): Pending; current MDEG license #: MP01128

Physical Address: 22100 Bothell Everett Highway

City: Bothell State: WA Zip: 98021

Mailing Address (if different from physical address): Philips Healthcare, Attn: Beth Rogers, 3000 Minuteman Road

City: Andover State: MA Zip: 01810

Telephone: 425-487-7900 Website: www.usa.philips.com/healthcare

Licensing Company Email: beth.c.rogers@philips.com

**Section 2: Personal Information**

First: Matthew Middle: Lee Last: Holttum

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: Philips Healthcare, Attn: Beth Rogers, 3000 Minuteman Road

City: Andover State: MA Zip: 01810

Telephone: [redacted] Email: matt.holttum@philips.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | From - To (MM/YY – MM/YY) | | |
|---|---|---|---|
| University of Washington | 08/85 - 05/88 | | |
| Address | City | State | Zip |
| 1410 NE Campus Parkway | Seattle | WA | 98195 |
| Diploma/Degree obtained, if any | | | |
| Bachelor of Arts (BA) - Business & Bachelor of Science (BS) - Psychology | | | |

| School Name | From - To (MM/YY – MM/YY) | | |
|---|---|---|---|
| Grays Harbor CC | 9/83 - 8/85 | | |
| Address | City | State | Zip |
| 1620 Edward P. Smith Dr | Aberdeen | WA | 98520 |
| Diploma/Degree obtained, if any | | | |
| Associate of Science (AS) | | | |

| School Name | From - To (MM/YY – MM/YY) | | |
|---|---|---|---|
| Aberdeen High School | 9/80 - 6/83 | | |
| Address | City | State | Zip |
| 500 N. G St. | Aberdeen | WA | 98520 |
| Diploma/Degree obtained, if any | | | |
| High School Diploma | | | |

| School Name | From - To (MM/YY – MM/YY) | | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | From - To (MM/YY – MM/YY) | | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 7/96 – DATE | [redacted] 43rd PL SW | Lynnwood | WA | 98087 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Philips Ultrasound LLC (f/k/a Philips Ultrasound, Inc.) | | | 07/91 - Present |
| **Business Address** | **City** | **State** | **Zip** |
| 22100 Bothell Everett Highway | Bothell | WA | 98021 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| 425-487-7836 | Director, System Operations | 40 hours per week | |
| **Description of Duties** | | | |
| Responsible for production lines and factory operations. | | | |

N/A

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

Continue on next page if additional space is needed.

N/A

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✓ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✓ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✓ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

N/A

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| Reason/Charge | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| Name of Business/Industry/Entity | | | | |

**Provide explanation below:**

Mark Hart
Original Signature (electronic, copies or stamps not accepted)

11/30/22
Date

I, Matthew L. Holttum, **certify that as the designated representative for**

Philips Ultrasound LLC,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. MH I am at least 21 years of age;
3. MH I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MH I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MH I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MH I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MH I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Matthew Holttum
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/30/22
Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Matthew Holttum

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/5/23

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of WA, ss. County of Snohomish

I, Matthew L. Holttum, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

1/5/23

**Date**

Subscribed and Sworn to before me this 5th day of January, 2023

**Notary Public Signature**

POLLY P HUTCHISON NOTARY PUBLIC STATE OF WASHINGTON COMMISSION EXPIRES 6-01-25 60585

**(Seal)**

## Employee List

Aaron Hendricks
Adam Kuhn
Adilene Escutia
Adrian Alcocer
Adriana Simicich
Ahmad Al-Rubaie
Alain Brown
Alden Papritz
Alejandro Gomez
Alex Eung
Ali Fazeli Toulami
Allan Yu
Amanda Lewis
Amy Cali
Andrew Hua
Andrew Tallian
Andy Baker
Anh Duc Dang
Rae Glasgow
Anthony Severin
Anubhuti Singh
April Buckner
Aqsa Patel
Ardeshir Ravani
Babken Kazanchyan
Basil Mohamed
Becki Allen
Ben Laurente
Benedict Callanta
Bill Blackie
Bofeng Zhang
Boyd Bien
Brad Buchanan
Brandon Haugh
Brandy Buerger
Brenda Calton
Brian Greeno
Brian Jubie
Brian Plebanek
Brian Ramey
Brian Siharath
Brice Mangkornkeo
Bridget Kovach
Bridgette Pittman
Brittany Mak
Brittany Mishra
Bunly Chhann
Cameron Stanley
Carl Cutter
Castulo Salazar
Catherine Sangco
Cesar Manalo
Chanh Nguyen
Channa Phoun Lan
Charlane Colson
Chen Jiang
Chen Selifis
Sherry Schlosser
Chhayleng Leng
Chot To
Chris Browne
Chris Teodoro
Christopher Acconcia
Christopher Haenisch
Christopher Myers
Chris Pease
Christopher Vodegel
Cierra Cameron
Clarissa Gunadharma
Cleo Maceda
Colton Terry
Cong Tran
Corrina Mahiai
Cuong Vo
Cyndi Read
Dale Walkingshaw
Dana Seckel
Daniel Ayala
Daniel Chhann
Daniel Hill
Dan Perreault
Daniela Espinosa
Danny Gee
Daphne Weeks
Dave Nguyen
Dave Werwinski
David Grimes
David Holm
David Lampert
David Raye
Dave Reid
Dave Scott
Debbie Godenzi
Debbie Scott
Denis Yapjoco
Devon Endsley
Devron Russell
Dieu-Hanh Del-Torchio
Dina Fawzy
Doug Holder
Duc Nguyen
Duy Pham
Dylan Salinas
Elise Borden
Elise Tibbits
Eteuati Michaels
Ezra Moon
Franklin Insouta
Gardee Fields
Gary Ng
George Gell
Gerald Brehmer
Gina Pham
Giovanni Quattrin

Gwendolynn Miller
Heidi Keoamphay
Helen Zheng
Hermenegilda Keomphay
Hoa Tran
Nam Le
Hoan Bui
Hugh Huang
Hung Le
Hung Nguyen
Huong Ha
Ian Davidson
ILYA OGORODNIK
Insu Choi
Itzel Rosales
Julia Sidorina
Jackie Sangco Rivera
Jacob Pak
Jacqueline Kam Yin Phung
Jagadeesh Attiganad
James Cerio
James Keogh
Jim Low
Jim O'Brien
Jamie Russell
Jang Lee
Jan DeBolt
Jason Cottle
Jason Peck
Jay Hollister
Jeffrey Beavers
Jeff Cohen
Jeffrey Voit
Jeffry Powers
Jennifer Pon Bourtaley
Jay Golveo
Jeremy Hahn
Jessica Johnson
Jet Sun
Jewel Lee
Jim Tuwun
John Morehead
Johnathan Tucker
Jonathan Bartsch
Jonathan Thongsamouth
Jong-Min Kim
Jordan Barnes
Jose Ayala
Joseph Chong
Joe Munn
Joshua Cortes
Joshua Lan
Josh Shadbolt
Juan Ayala
Juan Garingo III
Julie Seehaas
Jung Moon
Justin Chhour
Jyoti Kumari
Kailey Groat
Karen Fong
Katelyn Lutz
Katie Thien
Keisha Cook
Kelly Bowman
Ken Lorenzen
Kenny Cooksey
Kesem Zur-Korakin
Kevin Fitzgerald
Kevin McElwee
Khanh Nguyen
Khiet Nguyen
Khoi Le
Kil Vong
Kily Nhan
Kim Syharath
Kimheak Pav
Kimsan Kas
Krislynn Barnhart
Lakshmi Sanjana Gondesi
Laljit Singh
Lamdouane Keoamphay
Lance Proffit
Lauren D'Alessandro
Le Le
Lee Butler
Leif Flynn
Leslie Koski
Li Lu
Lida Nen
Liliana Barron
Lily Keomphay
Linda Macdicken
Lisa Hill
Loren Johnson
Luke Walker
Luz Ramirez
Maddie Sloan
Mahri Kadyrova
Makenzie Leibel
Maricris Ferrer
MARK GALLANAR
Mark Read
Mark Wanezek
Martijn Bos
Martin Bellman
Mary Nouansiri
Mason Lin
Mateo Antuna
Matthew Anderson
Matt Holttum
Matthew Rielly
Maxim Yerin
Melissa Huffaker
Melissa Portis
Mi Phan
Michael Hague
Michael Lutz
Michael Mock
Michael Nelson
Michael Pritchard
Michael Tanzil

Mikale Cummings
Miranda Benner
Mitchell Owens
Monika Wageman
Mugrach Touch
My Phung
My Tran
MyLinh Tran
Nam Hoang
Nate Eilertsen
Nathan Smith
Nathan Teodoro
Nga Huynh
Nhac Quach
Nhung Thi Trinh
Nhut Nguyen
Nicholas Allen
Nicodemus Holzer
Nikki Brown
Niraj Ladani
Nolan Eilertsen
Nouane Keoamphay
Patti Temple
Peter Goodman
Peter Hua
Peter Mahiai
Phong Nguyen
Grace To
Pisey Nop
Praphon Strickland
Prima Harding
Quang Ha
Nina Vu
Rachel Sanders
Raymond Gardner
Ray Kaler
Raymond Woods
Rebecca Mclaughlin
Reza Hosseinzadeh
Richard Sampson
Bob Menard
Ry Hong
Ryan Hayes
Sachiko White
Sam Freese
Sandi Scott-Moore
Sara Aurich
Sau Huynh
Scott Dimon
Scott Haffner
Scott Leckie
Scott Lennan
Scott Schick
Sean Mcelroy
Seema Dhaliwal
Sereyvuthy Suon
Seth Estabrook
Sharon Syska
Shannon Killion
Sharekia Harris
Shaun Goebel
Shaun Hall
Shuyi Huang
Silvestre Yrra
Simran Kaur
Sinh Van
Sisalinn Bou
Socheat Nou
Sohan Taing
Sokun Khim
Somkouane Keomphay
Somphan Aphaymany
Joe Makamanivong
Sopheap Duch
Sophia Juarez
Sovath Op
Spencer Paarlberg
Stephanie Braden
Steve Dilling
Todd Laffoon
Suo Muoy
Susan Kochanski
Terry Hansen
Thanasis Loupas
Thanh Bui
Thaoly Tran
Theresa Neighbors
Thoeurn Thoeuk
Thon Son
Thuong Nguyen
Thuy Nguyen
Tim Tran
Ting-Yu Lai
Tommy Miller
Trace Bartoli
Travis Kay
Tuan Hoang
Tuan Nguyen
Tuyen Nguyen
Tuyet Le
Victoria Metcalf
Vuong Bui
Duan Mebane
Waqas Khalid
Wei Lu
Wendy Reynolds
William Russell
Woonchul Choi
Wulfric Mangkornkeo
Xuan Tran To
Yoki Jiang
Yayun Wan
Yazmin Castaneda gonzalez
Yoko Shimizu
Frank Cheng
Zachary Engelbrecht

# 4T

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 (775) 850-1440

# Wholesaler Application

**Non-Refundable $1,000 Fee**

Rev (08/17/2022)

| | | |
|---|---|---|
| Where is the facility located? | | ☐ Nevada ☐ Out-of-State |
| **Type of Application (check applicable box)** | | **Wholesaler Business Type (check applicable box)** |
| ■ New Wholesaler<br>☐ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH _____ | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: PHOENIX ASSURANCE, LLC

Physical Address: 4835 MENDENHALL ROAD SOUTH

City: MEMPHIS State: TN Zip: 38141

Mailing Address (if different from physical address): 4750 PLEASANT HILL ROAD

City: MEMPHIS State: TN Zip: 38118

Telephone: 901-368-8940 Website: WWW.PHOENIXASSURANCE3PL.COM

Name of Designated Representative (DR): BRITANY DAVIS

Licensing Company Email: LICENSING4835@PA3PL.COM DR Email: BDAVIS@PA3PL.COM

| Entities the Wholesaler will Serve (✓ all applicable) | Products to be Handled or Wholesaled (✓ all applicable) | Type of Wholesaling (✓ all applicable) |
|---|---|---|
| ■ Pharmacies | ■ Dangerous Drugs | ☐ Manufacturer |
| ☐ Practitioners | ☐ Controlled Substances | ☐ Repacker |
| ■ Hospitals | ■ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ■ Wholesalers | ☐ Others: | ■ Warehouse |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ☐ Others: | | ☐ Others: |

| Section 2: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✔ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | ✔ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | ✔ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✔ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✔ |

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A Provide all the following *where applicable*:

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| N/A | N/A | N/A | N/A | N/A |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| N/A | | N/A | | |
| Reason/Charge | | | | |
| N/A | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| N/A | | | N/A | |
| Name of Business/Industry/Entity | | | | |
| N/A | | | | |

**Provide explanation below:**

N/A

Original Signature (electronic, copies or stamps not accepted)

6/29/23
Date

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: BAXTER HEALTHCARE
Address: 4109 MENDENHALL ROAD SOUTH City: MEMPHIS State: TN Zip: 38141
Name: N/A
Address: N/A City: N/A State: N/A Zip: N/A
Name: N/A
Address: N/A City: N/A State: N/A Zip: N/A
Name: N/A
Address: N/A City: N/A State: N/A Zip: N/A

**Section 4: Publicly Traded Corporation**

State of Incorporation: N/A
Parent Company (if any): N/A
Corporation Name: N/A
Mailing Address: N/A
City: N/A State: N/A Zip: N/A
Telephone: N/A Email: N/A
Contact Person Name: N/A

Date of SEC Registration: N/A | SEC Registration Number: N/A | Stock Exchange Symbol: N/A

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: TENNESSEE
Parent Company (if any): N/A
Corporation/Organization Name: PHOENIX ASSURANCE, LLC
Mailing Address: 4750 PLEASANT HILL ROAD
City: MEMPHIS State: TN Zip: 38118
Telephone: 901-368-8940 Email: LICENSING4835@PA3PL.COM
Contact Person Name: RITA PARKS

**Section 6: Partnership**

Partnership Name: N/A
Mailing Address: N/A
City: N/A State: N/A Zip: N/A
Telephone: N/A Email: N/A
Contact Person Name: N/A

**Section 7: Sole Owner**

Owner's Name: N/A
Business Name: N/A
Business Address: N/A
City: N/A State: N/A Zip: N/A
Telephone: N/A Email: N/A

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | ✓ |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | | ✓ |
| 1. Copy of FDA registration<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |

| **Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.** | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** | | ✓ | | |
| • **List of all partners and their percent ownership.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

PHOENIX ASSURANCE, LLC

Facility Name

RITA PARKS

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

6/29/23

Date

| Board Use Only | Date Received: 7-3-23 | Amount: 1000.00 CC |
|---|---|---|

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

# Drug Establishments Current Registration Site

New Search (default.cfm)

Search Results for **PHOENIX ASSURANCE**

CSVExcel

Filter:

| Firm Name | FDA Establishment Identifier | DUNS | Business Operations | Address | Expiration Date |
|---|---|---|---|---|---|
| Phoenix Assurance, LLC | 1039451 | 087115284 | RELABEL; REPACK; | 4750 Pleasant Hill Road, Memphis, Tennessee (TN) 38118, United States (USA) | 12/31/2023 |
| Phoenix Assurance, LLC | 1039451 | 118774169 | RELABEL; | 4835 Mendenhall Road South, Memphis, Tennessee (TN) 38141, United States (USA) | 12/31/2023 |
| Phoenix Assurance, LLC | 1039451 | 118774171 | RELABEL; REPACK; | 4755 Southpoint Drive Suite 101, Memphis, Tennessee (TN) 38118, United States (USA) | 12/31/2023 |
| Phoenix Assurance, LLC | 3023239120 | 106462017 | RELABEL; REPACK; | 22150 Goldencrest Dr., Moreno Valley, California (CA) 92553-9117, United States (USA) | 12/31/2023 |
| Phoenix Assurance, LLC | | 118982848 | RELABEL; REPACK; | 2700 Westport Parkway, Fort Worth, Texas (TX) 76177, United States (USA) | 12/31/2023 |

Showing 1 to 5 of 5 entries
Previous1Next
Data Current through: Monday, May 29, 2023

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

# Drug Establishments Current Registration Site

New Search (default.cfm)

Search Results for **Phoenix Assurance**

CSVExcel

Filter:

| Firm Name | FDA Establishment Identifier | DUNS | Business Operations | Address | Expiration Date |
|---|---|---|---|---|---|
| Phoenix Assurance, LLC | 1039451 | 118774171 | RELABEL; REPACK; | 4755 Southpoint Drive Suite 101, Memphis, Tennessee (TN) 38118, United States (USA) | 12/31/2023 |
| Phoenix Assurance, LLC | 1039451 | 118774169 | RELABEL; | 4835 Mendenhall Road South, Memphis, Tennessee (TN) 38141, United States (USA) | 12/31/2023 |
| Phoenix Assurance, LLC | 1039451 | 087115284 | RELABEL; REPACK; | 4750 Pleasant Hill Road, Memphis, Tennessee (TN) 38118, United States (USA) | 12/31/2023 |
| Phoenix Assurance, LLC | 3023239120 | 106462017 | RELABEL; REPACK; | 22150 Goldencrest Dr., Moreno Valley, California (CA) 92553-9117, United States (USA) | 12/31/2023 |
| Phoenix Assurance, LLC | | 118982848 | RELABEL; REPACK; | 2700 Westport Parkway, Fort Worth, Texas (TX) 76177, United States (USA) | 12/31/2023 |

Showing 1 to 5 of 5 entries
Previous1Next
Data Current through: Tuesday, Jun 6, 2023

Verified
6.7.23

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Phoenix Assurance LLC

Warehouse/Distribution

4755 SOUTHPOINT DR, SUITE 101
MEMPHIS, TN 38118

# Phoenix Assurance LLC - Officers

**Phoenix Assurance LLC** is:

- a Limited Liability Company registered in the State of Tennessee
- located at 4750 Pleasant Hill Road, Memphis, TN 38118
- Federal Employer Identification (FEI) number is 83-2706107
- State of Incorporation - Delaware

**Hulesy Britt – President / Managing Partner – 50%**

| Business: | Residence: |
|---|---|
| 4750 Pleasant Hill Road<br>Memphis, TN 38118<br>901-368-8942<br>hbritt@pa3pl.com | [redacted]<br>Memphis, TN 38103<br>[redacted] |

**Rita Parks - Vice President / Managing Partner – 50%**

| Business: | Residence: |
|---|---|
| 4750 Pleasant Hill Road<br>Memphis, TN 38118<br>901-368-8944<br>rparks@pa3pl.com | [redacted]<br>Corinth, MS 38835-0303<br>[redacted] |

**Tyler Kattawar – Chief Operating Officer**

| Business: | Residence: |
|---|---|
| 4105 S. Mendenhall Road<br>Memphis, TN 38115-5927<br>901-603-7539<br>tkattawar@kpowergl.com | [redacted]<br>Meadow Cove<br>Collierville, TN 38017<br>[redacted] |

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/13/2022)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of Pharmacy/MDEG/Wholesaler PHOENIX ASSURANCE, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable) N/A

Physical Address 4835 MENDENHALL ROAD SOUTH

City MEMPHIS State TN Zip 38141

Mailing Address (if different from physical address) 4750 PLEASANT HILL ROAD

City MEMPHIS State TN Zip 38118

Telephone 901-368-8940 Website WWW.PHONEIXASSURANCE3PL.COM

Licensing Company Email LICENSING4835@PA3PL.COM

**Section 2: Personal Information**

First RITA Middle POTTS Last PARKS

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted] PLEASANT HILL ROAD

City MEMPHIS State TN Zip 38118

Telephone 901-368-8944 Email RPARKS@PA3PL.COM

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✔ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| UNIVERSITY OF MISSISSIPPI | | | 1980-1985 | |
| **Address** | **City** | | **State** | **Zip** |
| UNIVERSITY CIRCLE | UNIVERSITY | | MS | 38677 |
| **Diploma/Degree obtained, if any** | | | | |
| BACHELOR OF SCIENCE-BIOLOGY | | | | |
| **School Name** | | | **From - To (MM/YY – MM/YY)** | |
| ALCORN HIGH SCHOOL | | | 1968-1974 | |
| **Address** | **City** | | **State** | **Zip** |
| 8 COUNTY ROAD 254 | GLEN | | MS | 38846 |
| **Diploma/Degree obtained, if any** | | | | |
| | | | | |
| **School Name** | | | **From - To (MM/YY – MM/YY)** | |
| N/A | | | N/A | |
| **Address** | **City** | | **State** | **Zip** |
| N/A | N/A | | N/A | N/A |
| **Diploma/Degree obtained, if any** | | | | |
| N/A | | | | |
| **School Name** | | | **From - To (MM/YY – MM/YY)** | |
| N/A | | | N/A | |
| **Address** | **City** | | **State** | **Zip** |
| N/A | N/A | | N/A | N/A |
| **Diploma/Degree obtained, if any** | | | | |
| N/A | | | | |
| **School Name** | | | **From - To (MM/YY – MM/YY** | |
| N/A | | | N/A | |
| **Address** | **City** | | **State** | **Zip** |
| N/A | N/A | | N/A | N/A |
| **Diploma/Degree obtained, if any** | | | | |
| N/A | | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 02-93-PRESENT | [redacted] COUNTY ROAD [redacted] | CORINTH | MS | 38834 |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | | N/A |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| PHOENIX ASSURANCE, LLC | | | 05-19-PRESENT | |
| **Business Address** | **City** | **State** | **Zip** | |
| 4750 PLEASANT HILL ROAD | MEMPHIS | TN | 38118 | |
| **Phone** | **Title** | | | |
| 901-368-8944 | VICE-PRESIDENT QUALITY/REGULATORY MANAGER | | | |
| **Description of Duties** | | | | |
| DIRECT, CONTROL, AND IMPLEMENT ALL REGULATORY ACTIVITIES | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| HIKMA PHARMACEUTICALS USA INC. | | | | |
| **Business Address** | **City** | **State** | **Zip** | |
| 4750 PLEASANT HILL ROAD | MEMPHIS | TN | 38118 | |
| **Phone** | **Title** | | | |
| 901-368-8940 | QUALITY/REGULATORY MANAGER | | | |
| **Description of Duties** | | | | |
| MANAGEMENT OF ALL QUALITY FUNCTIONS RELATED TO RECEIVING AND DISTRIBUTION | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| N/A | | | N/A | |
| **Business Address** | **City** | **State** | **Zip** | |
| N/A | N/A | N/A | N/A | |
| **Phone** | **Title** | | | |
| N/A | N/A | | | |
| **Description of Duties** | | | | |
| N/A | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| N/A | | | N/A | |
| **Business Address** | **City** | **State** | **Zip** | |
| N/A | N/A | N/A | N/A | |
| **Phone** | **Title** | | | |
| N/A | N/A | | | |
| **Description of Duties** | | | | |
| N/A | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| N/A | | | N/A | |
| **Business Address** | **City** | **State** | **Zip** | |
| N/A | N/A | N/A | N/A | |
| **Phone** | **Title** | | | |
| N/A | N/A | | | |
| **Description of Duties** | | | | |
| N/A | | | | |

Continue on next page if additional space is needed.

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| N/A | | N/A | |
| **Business Address** | **City** | **State** | **Zip** |
| N/A | N/A | N/A | N/A |
| **Phone** | **Title** | | |
| N/A | N/A | | |
| **Description of Duties** | | | |
| N/A | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| N/A | | N/A | |
| **Business Address** | **City** | **State** | **Zip** |
| N/A | N/A | N/A | N/A |
| **Phone** | **Title** | | |
| N/A | N/A | | |
| **Description of Duties** | | | |
| N/A | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| N/A | | N/A | |
| **Business Address** | **City** | **State** | **Zip** |
| N/A | N/A | N/A | N/A |
| **Phone** | **Title** | | |
| N/A | N/A | | |
| **Description of Duties** | | | |
| N/A | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| N/A | | N/A | |
| **Business Address** | **City** | **State** | **Zip** |
| N/A | N/A | N/A | N/A |
| **Phone** | **Title** | | |
| N/A | N/A | | |
| **Description of Duties** | | | |
| N/A | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| N/A | | N/A | |
| **Business Address** | **City** | **State** | **Zip** |
| N/A | N/A | N/A | N/A |
| **Phone** | **Title** | | |
| N/A | N/A | | |
| **Description of Duties** | | | |
| N/A | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question #** N/A **. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| N/A | N/A | N/A | N/A | N/A |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| N/A | | N/A | | |
| **Reason/Charge** | | | | |
| N/A | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| N/A | | | N/A | |
| **Name of Business/Industry/Entity** | | | | |
| N/A | | | | |

**Provide explanation below:**

N/A

Original Signature (electronic, copies or stamps not accepted)

Date 5/17/2023

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

RITA PARKS

Print Name (First, Last)

Rita Parks

Original Signature (electronic, copies or stamps not accepted)

5/17/2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of TENNESSEE, ss. County of SHELBY

I, LINNEA M HESS, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Rita Parks

**Original Signature**

5/17/2023

**Date**

Subscribed and Sworn to before me this 17th day of May.

**Notary Public Signature**

LINNEA M HESS
STATE OF TENNESSEE
NOTARY PUBLIC
My Commission Expires on 02/07/2027
SHELBY COUNTY

**(Seal)**

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/13/2022)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of Pharmacy/MDEG/Wholesaler PHOENIX ASSURANCE, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable) N/A

Physical Address 4835 MENDENHALL ROAD SOUTH

City MEMPHIS State TN Zip 38141

Mailing Address (if different from physical address) 4750 PLEASANT HILL ROAD

City MEMPHIS State TN Zip 38118

Telephone 901-368-8940 Website WWW.PHONEIXASSURANCE3PL.COM

Licensing Company Email LICENSING4835@PA3PL.COM

**Section 2: Personal Information**

First HULESY Middle _____ Last BRITT

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]PLEASANT HILL ROAD

City MEMPHIS State TN Zip 38118

Telephone 901-368-8940 Email HBRITT@PA3PL.COM

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✔ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| UNIVERSITY OF MEMPHIS | | 1994-1998 | |
| **Address** | **City** | **State** | **Zip** |
| 101 WILDER TOWER | MEMPHIS | TN | 38152 |
| **Diploma/Degree obtained, if any** | | | |
| N/A | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| TREZEVANT HIGH SCHOOL | | | |
| **Address** | **City** | **State** | **Zip** |
| 3350 NORTH TREZEVANT STREET | MEMPHIS | TN | 38127 |
| **Diploma/Degree obtained, if any** | | | |
| HIGH SCHOOL DIPLOMA | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| N/A | | N/A | |
| **Address** | **City** | **State** | **Zip** |
| N/A | N/A | N/A | N/A |
| **Diploma/Degree obtained, if any** | | | |
| N/A | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| N/A | | N/A | |
| **Address** | **City** | **State** | **Zip** |
| N/A | N/A | N/A | N/A |
| **Diploma/Degree obtained, if any** | | | |
| N/A | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| N/A | | N/A | |
| **Address** | **City** | **State** | **Zip** |
| N/A | N/A | N/A | N/A |
| **Diploma/Degree obtained, if any** | | | |
| N/A | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 09/19-PRESENT | [redacted]MARTIN LUTHER KING JR AVE #465 | MEMPHIS | TN | 38103 |
| 02/15-09/19 | [redacted]SOUTH MAIN STREET #417 | MEMPHIS | TN | 38103 |
| 01/07-02/15 | [redacted] SHOEMAKER COURT #108 | MEMPHIS | TN | 38103 |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| PHOENIX ASSURANCE, LLC | | | 05/19-PRESENT |
| **Business Address** | **City** | **State** | **Zip** |
| 4750 PLEASANT HILL ROAD | MEMPHIS | TN | 38118 |
| **Phone** | **Title** | | |
| 901-368-8940 | PRESIDENT | | |

Description of Duties

Developing and implementing quality policies and procedures, ensuring quality inspections of prescription drugs are processed and in compliance with procedures; ensuring suspicious &/or potentially illegitimate prescription drug products are quarantined and appropriate notifications to the FDA are completed as required; ensuring inventory of all drug products, including controlled substances, are accurate and in the state of control.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| HIKMA PHARMEUTICALS USA INC. | | | |
| **Business Address** | **City** | **State** | **Zip** |
| 4750 PLEASANT HILL ROAD | MEMPHIS | TN | 38118 |
| **Phone** | **Title** | | |
| 901-368-8940 | FACILITY OPERATIONS MANAGER | | |

Description of Duties

Highly experienced professional with more than 20 years working in the Distribution Industry in the supervisor or management position with a proven record of administration and interaction within the discipline. Experience includes: strategic planning, project management, production, knowledge of FDA regulations,current Good Manufacturing Practices (cGMP), Standard Operating Procedures (SOP), statistical process control, DEA Regulations, and the development of control plans.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| N/A | | | N/A |
| **Business Address** | **City** | **State** | **Zip** |
| N/A | N/A | N/A | N/A |
| **Phone** | **Title** | | |
| N/A | N/A | | |

Description of Duties

N/A

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| N/A | | | N/A |
| **Business Address** | **City** | **State** | **Zip** |
| N/A | N/A | N/A | N/A |
| **Phone** | **Title** | | |
| N/A | N/A | | |

Description of Duties

N/A

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| N/A | | | N/A |
| **Business Address** | **City** | **State** | **Zip** |
| N/A | N/A | N/A | N/A |
| **Phone** | **Title** | | |
| N/A | N/A | | |

Description of Duties

N/A

Continue on next page if additional space is needed.

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| N/A | | N/A | |
| **Business Address** | **City** | **State** | **Zip** |
| N/A | N/A | N/A | N/A |
| **Phone** | **Title** | | |
| N/A | N/A | | |
| **Description of Duties** | | | |
| N/A | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| N/A | | N/A | |
| **Business Address** | **City** | **State** | **Zip** |
| N/A | N/A | N/A | N/A |
| **Phone** | **Title** | | |
| N/A | N/A | | |
| **Description of Duties** | | | |
| N/A | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| N/A | | N/A | |
| **Business Address** | **City** | **State** | **Zip** |
| N/A | N/A | N/A | N/A |
| **Phone** | **Title** | | |
| N/A | N/A | | |
| **Description of Duties** | | | |
| N/A | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| N/A | | N/A | |
| **Business Address** | **City** | **State** | **Zip** |
| N/A | N/A | N/A | N/A |
| **Phone** | **Title** | | |
| N/A | N/A | | |
| **Description of Duties** | | | |
| N/A | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| N/A | | N/A | |
| **Business Address** | **City** | **State** | **Zip** |
| N/A | N/A | N/A | N/A |
| **Phone** | **Title** | | |
| N/A | N/A | | |
| **Description of Duties** | | | |
| N/A | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question #** N/A **. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| N/A | N/A | N/A | N/A | N/A |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| N/A | | N/A | | |
| **Reason/Charge** | | | | |
| N/A | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| N/A | | | N/A | |
| **Name of Business/Industry/Entity** | | | | |
| N/A | | | | |

**Provide explanation below:**

N/A

Original Signature (electronic, copies or stamps not accepted)

5/16/2023
Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

HULESY BRITT

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/16/2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of TENNESSEE, ss. County of SHELBY

I, LINNEA M HESS, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

5/16/2023

**Date**

Subscribed and Sworn to before me this 16th day of MAY.

**Notary Public Signature**

LINNEA M HESS
STATE OF TENNESSEE
NOTARY PUBLIC
My Commission Expires on 02/07/2027
SHELBY COUNTY

**(Seal)**

Tre Hargett
Secretary of State

**Division of Business Services**
**Department of State**
State of Tennessee
312 Rosa L. Parks AVE, 6th FL
Nashville, TN 37243-1102

**JEANNIE JONES**
4750 PLEASANT HILL ROAD
MEMPHIS, TN 38118

April 4, 2023

**Request Type:** Certificate of Existence/Authorization
Request #: 0523956

Issuance Date: 04/04/2023
Copies Requested: 1

**Document Receipt**

Receipt # : 008018148

Filing Fee: $20.00

Payment-Credit Card - State Payment Center - CC # [redacted] $20.00

**Regarding:** **Phoenix Assurance, LLC**

Filing Type: Limited Liability Company - Domestic
Formation/Qualification Date: 10/19/2018
Status: Active
Duration Term: Perpetual
Business County: SHELBY COUNTY

Control # : 990901
Date Formed: 10/19/2018
Formation Locale: TENNESSEE
Inactive Date:

## CERTIFICATE OF EXISTENCE

I, Tre Hargett, Secretary of State of the State of Tennessee, do hereby certify that effective as of the issuance date noted above

**Phoenix Assurance, LLC**

* is a Limited Liability Company duly formed under the law of this State with a date of incorporation and duration as given above;

* has paid all fees, interest, taxes and penalties owed to this State (as reflected in the records of the Secretary of State and the Department of Revenue) which affect the existence/authorization of the business;

* has filed the most recent annual report required with this office;

* has appointed a registered agent and registered office in this State;

* has not filed Articles of Dissolution or Articles of Termination. A decree of judicial dissolution has not been filed.

Tre Hargett
Secretary of State

Processed By: Cert Web User

**Verification #: 059830929**

TENNESSEE DEPARTMENT OF HEALTH
DIVISION OF HEALTH RELATED BOARDS

ID NUMBER: 0000007973
EXPIRATION DATE: 06/30/2024

*This is to certify that all requirements of the State of Tennessee have been met*

PHARMACY BOARD
THIRD PARTY LOGISTICS
PHOENIX ASSURANCE, LLC

COMMISSIONER OF HEALTH

RITA PARKS
PHOENIX ASSURANCE, LLC
4750 PLEASANT HILL ROAD
MEMPHIS TN 38118-7809

13019369
31608

State of Tennessee
Department of Health

BOARD OF PHARMACY
THIRD PARTY LOGISTICS
PHOENIX ASSURANCE, LLC
4835 MENDENHALL ROAD SOUTH
MEMPHIS TN 38141

*This is to certify that all requirements of the State of Tennessee have been met*

ID NUMBER: 0000007973
EXPIRATION DATE: 06/30/2024

ASSISTANT COMMISSIONER, HEALTH LICENSURE & REGULATION

COMMISSIONER

DCF171

Client#: 1843041 PHOENASS3

# ACORD™ CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 5/09/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer any rights to the certificate holder in lieu of such endorsement(s).

| PRODUCER | CONTACT NAME: Laura E. Paylor |
|---|---|
| USI Insurance Services LLC /CL<br>5100 Poplar Avenue, #1200<br>Memphis, TN 38137<br>901 766-5990 | PHONE (A/C, No, Ext): 901-412-1033 FAX (A/C, No):<br>E-MAIL ADDRESS: Laura.Paylor@usi.com |

| INSURED | INSURER(S) AFFORDING COVERAGE | NAIC # |
|---|---|---|
| Phoenix Assurance LLC<br>4750 Pleasan Hill Rd.<br>Memphis, TN 38118 | INSURER A : Ohio Security Insurance Company | 24082 |
| | INSURER B : Ohio Casualty Insurance Company | 24074 |
| | INSURER C : Insurance Company of the West | 27847 |
| | INSURER D : Lexington Insurance Company | 19437 |
| | INSURER E : Aspen Specialty Insurance Company | 10717 |
| | INSURER F : Atlantic Specialty Insurance Company | 35378 |

**COVERAGES** **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

| INSR LTR | TYPE OF INSURANCE | ADDL INSR | SUBR WVD | POLICY NUMBER | POLICY EFF (MM/DD/YYYY) | POLICY EXP (MM/DD/YYYY) | LIMITS | |
|---|---|---|---|---|---|---|---|---|
| A | X COMMERCIAL GENERAL LIABILITY | | | BKS2359595191 | 05/08/2023 | 05/08/2024 | EACH OCCURRENCE | $1,000,000 |
| | CLAIMS-MADE X OCCUR | | | | | | DAMAGE TO RENTED PREMISES (Ea occurrence) | $500,000 |
| | | | | | | | MED EXP (Any one person) | $15,000 |
| | | | | | | | PERSONAL & ADV INJURY | $1,000,000 |
| | GEN'L AGGREGATE LIMIT APPLIES PER: | | | | | | GENERAL AGGREGATE | $2,000,000 |
| | X POLICY PRO-JECT LOC | | | | | | PRODUCTS - COMP/OP AGG | $2,000,000 |
| | OTHER: | | | | | | | $ |
| | AUTOMOBILE LIABILITY | | | | | | COMBINED SINGLE LIMIT (Ea accident) | $ |
| | ANY AUTO | | | | | | BODILY INJURY (Per person) | $ |
| | OWNED AUTOS ONLY / SCHEDULED AUTOS | | | | | | BODILY INJURY (Per accident) | $ |
| | HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY | | | | | | PROPERTY DAMAGE (Per accident) | $ |
| | | | | | | | | $ |
| B | X UMBRELLA LIAB X OCCUR | | | USO2359595191 | 05/08/2023 | 05/08/2024 | EACH OCCURRENCE | $5,000,000 |
| | EXCESS LIAB CLAIMS-MADE | | | | | | AGGREGATE | $5,000,000 |
| | DED X RETENTION $10,000 | | | | | | | $ |
| C | WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N | | | WTE507120100 | 05/08/2023 | 05/08/2024 | X PER STATUTE OTH-ER | |
| | ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N / N/A | | | | | | E.L. EACH ACCIDENT | $1,000,000 |
| | (Mandatory in NH) | | | | | | E.L. DISEASE - EA EMPLOYEE | $1,000,000 |
| | If yes, describe under DESCRIPTION OF OPERATIONS below | | | | | | E.L. DISEASE - POLICY LIMIT | $1,000,000 |
| D | Warehousemen | | | 51567126 | 01/22/2023 | 01/22/2024 | $10,000,000 | |
| E | Warehousemen | | | IM00KNM23 | 01/22/2023 | 01/22/2024 | $10M X $10M | |
| F | Warehousemen | | | 7900323140002 | 01/22/2023 | 01/22/2024 | $30 X $20M | |

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

G) Pollution Policy # MKLV2ENV102817 Eff Date; 6/1/2022 Exp Date 6/1/2023 Limit: $2,000,000
Carrier: Evanston Insurance Company NAIC#35378
H) Errors & Omission/Professional Liability Eff Date: 11/1/2022 Exp Date: 11/1/2023- Limit 5,000,000
Carrier: North River Insurance Company NAIC#21105
Locations On Warehouse Legal:
(See Attached Descriptions)

**CERTIFICATE HOLDER**

Insured's Copy

**CANCELLATION**

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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## DESCRIPTIONS (Continued from Page 1)

19972 Patterson Ave., Perris CA 92570
22150 Goldencrest Dr., Moreno Valley, CA 92533
200 Interstate S, S180, McDonough GA 30253
4835 S. Mendenhall, Memphis TN 38141
4750 Pleasan Hill Rd. Memphis TN 38118
4755 Southpoint, Memphis TN 38118
4059 Pilot Drive, Memphis TN 38118

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

## PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. PB11499808958

Application/License No. WH00238

PHOENIX ASSURANCE, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 4750 PLEASANT HILL RD, MEMPHIS, TN, 38118 (Address of Applicant/Principal), as PRINCIPAL, and Philadelphia Indemnity Insurance Company (Surety Company), a corporation organized under the laws of the state of Pennsylvania (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Bala Plaza, Suite 100 BALA CYNWYD PA 19004 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on Mar 01, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 03rd day of March, 20 23.

APPLICANT/PRINCIPAL
PHOENIX ASSURANCE, LLC
COMPANY

Authorized Representative

SIGNED and SEALED in the presence of:

Witness

Witness

SURETY
Philadelphia Indemnity Insurance Company

Surety Company's Representative

John D. Weisbrot, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

PHILADELPHIA INDEMNITY INSURANCE COMPANY ★ PENNSYLVANIA ★ CORPORATE SEAL 1927

Posted February 20, 2020

PHILADELPHIA
INSURANCE COMPANIES

Philadelphia Indemnity Insurance Company
One Bala Plaza, Suite 100
Bala Cynwyd, PA 19004

# BOND RIDER

**Bond No:** PB11499808958

**Principal:** Phoenix Assurance, LLC

**Obligee:** The State of Nevada and to the Nevada State Board of Pharmacy

**Surety:** Philadelphia Indemnity Insurance Company

**Effective:** 03/03/2023

**It is agreed that:** Adding Three Locations:
4755 Southpoint Drive, Memphis, TN 38118
4835 S Mendenhall Rd., Memphis, TN 38141
22150 Goldencrest Drive, Moreno Valley, CA 92553

**Nothing herein contained shall be held to vary, waive, alter, or extend any of the terms, conditions, agreements or warranties of the above mentioned bond, other than stated as above. Provided, however, that the liability of the company under the attached bond as changed by this order shall not be cumulative.**

**Signed this** 3rd **day of** March **. 20** 23 **.**

**Principal:**

**By:** _____
**Principal Signature**

**Philadelphia Indemnity Insurance Company**

**By:** _____
John D. Weisbrot, **Attorney In Fact**

**PHILADELPHIA INDEMNITY INSURANCE COMPANY**
One Bala Plaza, Suite 100
Bala Cynwyd, PA 19004-0950

**Power of Attorney**

KNOW ALL PERSONS BY THESE PRESENTS: That **PHILADELPHIA INDEMNITY INSURANCE COMPANY** (the Company), a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, does hereby constitute and appoint JOHN D. WEISBROT, MELISSA L. MCDADE OR STEVEN M. VARGA its true and lawful Attorney-in-fact with full authority to execute on its behalf bonds, undertakings, recognizances and other contracts of indemnity and writings obligatory in the nature thereof, issued in the course of its business and to bind the Company thereby, in an amount not to exceed $50,000,000.

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of PHILADELPHIA INDEMNITY INSURANCE COMPANY on the 14th of November, 2016.

**RESOLVED:** That the Board of Directors hereby authorizes the President or any Vice President of the Company: (1) Appoint Attorney(s) in Fact and authorize the Attorney(s) in Fact to execute on behalf of the Company bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof and to attach the seal of the Company thereto; and (2) to remove, at any time, any such Attorney-in-Fact and revoke the authority given. And, be it

**FURTHER RESOLVED:** That the signatures of such officers and the seal of the Company may be affixed to any such Power of Attorney or certificate relating thereto by facsimile, and any such Power of Attorney so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking to which it is attached."

IN TESTIMONY WHEREOF, PHILADELPHIA INDEMNITY INSURANCE COMPANY HAS CAUSED THIS INSTRUMENT TO BE SIGNED AND ITS CORPORATE SEAL TO BE AFFIXED BY ITS AUTHORIZED OFFICE THIS 5TH DAY OF MARCH, 2021.

(Seal)

John Glomb, President & CEO
Philadelphia Indemnity Insurance Company

On this 5th day of March, 2021 before me came the individual who executed the preceding instrument, to me personally known, and being by me duly sworn said that he is the therein described and authorized officer of the **PHILADELPHIA INDEMNITY INSURANCE COMPANY**; that the seal affixed to said instrument is the Corporate seal of said Company; that the said Corporate Seal and his signature were duly affixed.

Notary Public: Vanessa McKenzie

Commonwealth of Pennsylvania - Notary Seal
Vanessa Mckenzie, Notary Public
Montgomery County
My commission expires November 3, 2024
Commission number 1358394
Member, Pennsylvania Association of Notaries

residing at: Bala Cynwyd, PA

My commission expires: November 3, 2024

I, Edward Sayago, Corporate Secretary of PHILADELPHIA INDEMNITY INSURANCE COMPANY, do hereby certify that the foregoing resolution of the Board of Directors and the Power of Attorney issued pursuant thereto on the 5th day March, 2021 are true and correct and are still in full force and effect. I do further certify that John Glomb, who executed the Power of Attorney as President, was on the date of execution of the attached Power of Attorney the duly elected President of PHILADELPHIA INDEMNITY INSURANCE COMPANY.

In Testimony Whereof I have subscribed my name and affixed the facsimile seal of each Company this 03rd day of March 20 23

Edward Sayago, Corporate Secretary
**PHILADELPHIA INDEMNITY INSURANCE COMPANY**

To verify the bond please visit https://www.suretybond.org/validate/?code=ekIX2Qld2JB1kJA1IWXA17Dg&transaction=XFkG0VQV16cwheQwRcVVdJCQ

DocuSign Envelope ID: 80E6D0FD-F56E-4105-9012-5C726351A08C

# PHILADELPHIA INDEMNITY INSURANCE COMPANY

## Statutory Statements of Admitted Assets, Liabilities and Capital and Surplus
## (in thousands, except par value and share amounts)

| Admitted Assets | As of December 31, 2021 | 2020 |
|---|---|---|
| Bonds (fair value $8,447,694 and $8,041,263) | $ 8,102,442 | $ 7,601,946 |
| Preferred stocks (fair value $19,262 and $16,537) | 19,262 | 15,673 |
| Common stocks (cost $44,923 and $52,609) | 43,194 | 43,373 |
| Mortgage loans | 957,986 | 821,250 |
| Real estate | 29,408 | 29,973 |
| Other invested assets (cost $194,229 and $203,028) | 218,926 | 215,589 |
| Receivables for securities sold | 152 | 943 |
| Cash, cash equivalents and short-term investments | 128,587 | 34,279 |
| Cash and invested assets | 9,499,957 | 8,763,026 |
| Premiums receivable, agents' balances and other receivables | 914,676 | 908,602 |
| Reinsurance recoverable on paid loss and loss adjustment expenses | 45,200 | 38,737 |
| Accrued investment income | 74,000 | 74,070 |
| Receivable from affiliates | 5,171 | 7,586 |
| Federal income taxes receivable | 8,144 | - |
| Net deferred tax assets | 141,943 | 138,129 |
| Other assets | 9,953 | 4,997 |
| Total admitted assets | $ 10,699,044 | $ 9,935,147 |

| Liabilities and Capital and Surplus | | |
|---|---|---|
| Liabilities: | | |
| Unpaid loss and loss adjustment expenses | $ 5,436,808 | $ 5,218,304 |
| Unearned premiums | 1,658,339 | 1,582,116 |
| Reinsurance payable on paid loss and loss adjustment expenses | 35,820 | 30,398 |
| Ceded reinsurance premiums payable | 130,474 | 108,936 |
| Commissions payable, contingent commissions and other similar charges | 228,628 | 214,389 |
| Federal income taxes payable | - | 8,480 |
| Funds held | 77,317 | 77,256 |
| Payable to affiliates | 19,465 | 18,486 |
| Provision for reinsurance | 471 | 87 |
| Payable for securities purchased | 19,045 | 17,820 |
| Accrued expenses and other liabilities | 47,213 | 32,170 |
| Total liabilities | 7,653,580 | 7,308,442 |
| Capital: | | |
| Common stock, par value of $10 per share; 1,000,000 shares authorized, 450,000 shares issued and outstanding | 4,500 | 4,500 |
| Surplus: | | |
| Gross paid-in and contributed surplus | 386,071 | 386,071 |
| Unassigned surplus | 2,654,893 | 2,236,134 |
| Total surplus | 3,040,964 | 2,622,205 |
| Total capital and surplus | 3,045,464 | 2,626,705 |
| Total liabilities and capital and surplus | $ 10,699,044 | $ 9,935,147 |

The undersigned, being duly sworn, says: That she is the Executive Vice President and Chief Financial Officer of Philadelphia Indemnity Insurance Company; that said Company is a corporation duly organized in the state of Pennsylvania, and licensed and engaged in the State of Pennsylvania and has duly complied with all the requirements of the laws of the said State applicable of the said Company and is duly qualified to act as Surety under such laws; that said Company has also complied with and is duly qualified to act as Surety under the Act of Congress. And that to the best of her knowledge and belief the above statement is a full, true and correct statement of

Attest:

DocuSigned by:
Karen Gilmer-Pauciello
Karen Gilmer-Pauciello, EVP & CFO

Sworn to before me this 2nd day of June 2022.

Kimberly Kessleski, Notary

Commonwealth of Pennsylvania - Notary Seal
Kimberly A. Kessleski, Notary Public
Montgomery County
My commission expires December 18, 2024
Commission number 1245769
Member, Pennsylvania Association of Notaries

**PHILADELPHIA INDEMNITY INSURANCE COMPANY**
One Bala Plaza, Suite 100
Bala Cynwyd, PA 19004-0950

**Power of Attorney**

KNOW ALL PERSONS BY THESE PRESENTS: That **PHILADELPHIA INDEMNITY INSURANCE COMPANY** (the Company), a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, does hereby constitute and appoint JOHN D. WEISBROT, MELISSA L. MCDADE OR STEVEN M. VARGA its true and lawful Attorney-in-fact with full authority to execute on its behalf bonds, undertakings, recognizances and other contracts of indemnity and writings obligatory in the nature thereof, issued in the course of its business and to bind the Company thereby, in an amount not to exceed $50,000,000.

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of PHILADELPHIA INDEMNITY INSURANCE COMPANY on the 14th of November, 2016.

**RESOLVED:** That the Board of Directors hereby authorizes the President or any Vice President of the Company: (1) Appoint Attorney(s) in Fact and authorize the Attorney(s) in Fact to execute on behalf of the Company bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof and to attach the seal of the Company thereto; and (2) to remove, at any time, any such Attorney-in-Fact and revoke the authority given. And, be it

**FURTHER RESOLVED:** That the signatures of such officers and the seal of the Company may be affixed to any such Power of Attorney or certificate relating thereto by facsimile, and any such Power of Attorney so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking to which it is attached.

IN TESTIMONY WHEREOF, PHILADELPHIA INDEMNITY INSURANCE COMPANY HAS CAUSED THIS INSTRUMENT TO BE SIGNED AND ITS CORPORATE SEALTO BE AFFIXED BY ITS AUTHORIZED OFFICE THIS 5TH DAY OF MARCH, 2021.

(Seal)

John Glomb, President & CEO
Philadelphia Indemnity Insurance Company

On this 5th day of March, 2021 before me came the individual who executed the preceding instrument, to me personally known, and being by me duly sworn said that he is the therein described and authorized officer of the **PHILADELPHIA INDEMNITY INSURANCE COMPANY**; that the seal affixed to said instrument is the Corporate seal of said Company; that the said Corporate Seal and his signature were duly affixed.

Commonwealth of Pennsylvania - Notary Seal
Vanessa Mckenzie, Notary Public
Montgomery County
My commission expires November 3, 2024
Commission number 1366394
Member, Pennsylvania Association of Notaries

Notary Public: Vanessa McKenzie

residing at: Bala Cynwyd, PA

My commission expires: November 3, 2024

I, Edward Sayago, Corporate Secretary of PHILADELPHIA INDEMNITY INSURANCE COMPANY, do hereby certify that the foregoing resolution of the Board of Directors and the Power of Attorney issued pursuant thereto on the 5th day March, 2021 are true and correct and are still in full force and effect. I do further certify that John Glomb, who executed the Power of Attorney as President, was on the date of execution of the attached Power of Attorney the duly elected President of PHILADELPHIA INDEMNITY INSURANCE COMPANY.

In Testimony Whereof I have subscribed my name and affixed the facsimile seal of each Company this 3rd day of March 20 23

Edward Sayago, Corporate Secretary
**PHILADELPHIA INDEMNITY INSURANCE COMPANY**

DocuSign Envelope ID: 80E6D0FD-F56E-4105-9012-5C726351A08C

# PHILADELPHIA INDEMNITY INSURANCE COMPANY

## Statutory Statements of Admitted Assets, Liabilities and Capital and Surplus
**(in thousands, except par value and share amounts)**

| Admitted Assets | As of December 31, 2021 | 2020 |
|---|---|---|
| Bonds (fair value $8,447,694 and $8,041,263) | $ 8,102,442 | $ 7,601,946 |
| Preferred stocks (fair value $19,262 and $16,537) | 19,262 | 15,673 |
| Common stocks (cost $41,923 and $52,689) | 43,194 | 43,373 |
| Mortgage loans | 957,986 | 821,250 |
| Real estate | 29,408 | 29,973 |
| Other invested assets (cost $194,229 and $203,028) | 218,926 | 215,589 |
| Receivables for securities sold | 152 | 913 |
| Cash, cash equivalents and short-term investments | 128,587 | 34,279 |
| Cash and invested assets | 9,499,957 | 8,763,026 |
| Premiums receivable, agents' balances and other receivables | 914,676 | 968,602 |
| Reinsurance recoverable on paid loss and loss adjustment expenses | 45,200 | 38,717 |
| Accrued investment income | 74,000 | 74,070 |
| Receivable from affiliates | 5,171 | 7,586 |
| Federal income taxes receivable | 8,141 | - |
| Net deferred tax assets | 141,943 | 138,129 |
| Other assets | 9,953 | 4,992 |
| Total admitted assets | $ 10,699,044 | $ 9,935,147 |

| Liabilities and Capital and Surplus | | |
|---|---|---|
| Liabilities: | | |
| Unpaid loss and loss adjustment expenses | $ 5,436,808 | $ 5,218,304 |
| Unearned premiums | 1,658,339 | 1,582,116 |
| Reinsurance payable on paid loss and loss adjustment expenses | 35,820 | 30,398 |
| Ceded reinsurance premiums payable | 130,474 | 108,936 |
| Commissions payable, contingent commissions and other similar charges | 228,628 | 214,389 |
| Federal income taxes payable | - | 8,480 |
| Funds held | 77,317 | 77,256 |
| Payable to affiliates | 19,465 | 18,486 |
| Provision for reinsurance | 471 | 87 |
| Payable for securities purchased | 19,045 | 17,820 |
| Accrued expenses and other liabilities | 47,213 | 32,170 |
| Total liabilities | 7,653,580 | 7,308,442 |
| Capital: | | |
| Common stock, par value of $10 per share; 1,000,000 shares authorized, 450,000 shares issued and outstanding | 4,500 | 4,500 |
| Surplus: | | |
| Gross paid-in and contributed surplus | 386,071 | 386,071 |
| Unassigned surplus | 2,654,893 | 2,236,134 |
| Total surplus | 3,040,964 | 2,622,205 |
| Total capital and surplus | 3,045,464 | 2,626,705 |
| Total liabilities and capital and surplus | $ 10,699,044 | $ 9,935,147 |

The undersigned, being duly sworn, says: That she is the Executive Vice President and Chief Financial Officer of Philadelphia Indemnity Insurance Company; that said Company is a corporation duly organized in the state of Pennsylvania, and licensed and engaged in the State of Pennsylvania and has duly complied with all the requirements of the laws of the said State applicable of the said Company and is duly qualified to act as Surety under such laws; that said Company has also complied with and is duly qualified to act as Surety under the Act of Congress. And that to the best of her knowledge and belief the above statement is a full, true and correct statement of

Attest:

DocuSigned by:
Karen Gilmer-Pauciello
Karen Gilmer-Pauciello, EVP & CFO

Sworn to before me this 2nd day of June 2022.

Kimberly Kessleski, Notary

Commonwealth of Pennsylvania - Notary Seal
Kimberly A. Kessleski, Notary Public
Montgomery County
My commission expires December 18, 2024
Commission number 1245769
Member, Pennsylvania Association of Notaries

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

# Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of MDEG PHOENIX ASSURANCE, LLC MDEG License # (if applicable) N/A

Physical Address 4835 MENDENHALL RD SOUTH

City MEMPHIS State TN Zip 38141

Mailing Address (if different from physical address) 4750 PLEASANT HILL RD

City MEMPHIS State TN Zip 38118

Telephone 901-368-8940 Website WWW.PHOENIXASSURANCE3PL.COM

Licensing Company Email LICENSING4835@PA3PL.COM

**Section 2: Personal Information**

First BRITANY Middle JO Last DAVIS

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address 4835 MENDENHALL RD SOUTH

City MEMPHIS State TN Zip 38141

Telephone 901-368-8967 Email BDAVIS@PA3PL.COM

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| UT MEMPHIS | | 08/99-05/00 | |
| **Address** | **City** | **State** | **Zip** |
| 920 MADISON AVE, SUITE 807 | MEMPHIS | TN | 38163 |
| Diploma/Degree obtained, if any | | | |
| N/A | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| UNION UNIVERSITY | | 08/95-05/99 | |
| **Address** | **City** | **State** | **Zip** |
| 1050 UNION UNIVERSITY DRIVE | JACKSON | TN | 38305 |
| Diploma/Degree obtained, if any | | | |
| BACHELOR OF SCIENCE | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| WESTVIEW HIGH SCHOOL | | 08/91-05/95 | |
| **Address** | **City** | **State** | **Zip** |
| 8161 HIGHWAY 45 | MARTIN | TN | 38305 |
| Diploma/Degree obtained, if any | | | |
| N/A | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| N/A | | N/A | |
| **Address** | **City** | **State** | **Zip** |
| N/A | N/A | N/A | N/A |
| Diploma/Degree obtained, if any | | | |
| N/A | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| N/A | | N/A | |
| **Address** | **City** | **State** | **Zip** |
| N/A | N/A | N/A | N/A |
| Diploma/Degree obtained, if any | | | |
| N/A | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 2011-PRESENT | [redacted] DOUGLAS DRIVE | OLIVE BRANCH | MS | 38654 |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |

**Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| PHOENIX ASSURANCE, LLC | | | 08/19-PRESENT | |
| **Business Address** | | **City** | **State** | **Zip** |
| 4835 MENDENHALL ROAD SOUTH | | MEMPHIS | TN | 38141 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 901-368-8940 | DESIGNATED REPRESENTATIVE | | | |
| **Description of Duties** | | | | |
| DIRECT, CONTROL AND IMPLEMENT ALL REGULATORY ACTIVITIES | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| N/A | | | N/A | |
| **Business Address** | | **City** | **State** | **Zip** |
| N/A | | N/A | N/A | N/A |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| N/A | N/A | | N/A | |
| **Description of Duties** | | | | |
| N/A | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| N/A | | | N/A | |
| **Business Address** | | **City** | **State** | **Zip** |
| N/A | | N/A | N/A | N/A |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| N/A | N/A | | N/A | |
| **Description of Duties** | | | | |
| N/A | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| N/A | | | N/A | |
| **Business Address** | | **City** | **State** | **Zip** |
| N/A | | N/A | N/A | N/A |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| N/A | N/A | | N/A | |
| **Description of Duties** | | | | |
| N/A | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| N/A | | | N/A | |
| **Business Address** | | **City** | **State** | **Zip** |
| N/A | | N/A | N/A | N/A |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| N/A | N/A | | N/A | |
| **Description of Duties** | | | | |
| N/A | | | | |

Continue on next page if additional space is needed.

| Business Name | | From - To (MM/YY – MM/YY) |
|---|---|---|
| N/A | | N/A |
| **Business Address** | **City** | **State** / **Zip** |
| N/A | N/A | N/A / N/A |
| **Phone** | **Title** | **Number of Employed Hours** |
| N/A | N/A | N/A |
| **Description of Duties** | | |
| N/A | | |

| Business Name | | From - To (MM/YY – MM/YY) |
|---|---|---|
| N/A | | N/A |
| **Business Address** | **City** | **State** / **Zip** |
| N/A | N/A | N/A / N/A |
| **Phone** | **Title** | **Number of Employed Hours** |
| N/A | N/A | N/A |
| **Description of Duties** | | |
| N/A | | |

| Business Name | | From - To (MM/YY – MM/YY) |
|---|---|---|
| N/A | | N/A |
| **Business Address** | **City** | **State** / **Zip** |
| N/A | N/A | N/A / N/A |
| **Phone** | **Title** | **Number of Employed Hours** |
| N/A | N/A | N/A |
| **Description of Duties** | | |
| N/A | | |

| Business Name | | From - To (MM/YY – MM/YY) |
|---|---|---|
| N/A | | N/A |
| **Business Address** | **City** | **State** / **Zip** |
| N/A | N/A | N/A / N/A |
| **Phone** | **Title** | **Number of Employed Hours** |
| N/A | N/A | N/A |
| **Description of Duties** | | |
| N/A | | |

| Business Name | | From - To (MM/YY – MM/YY) |
|---|---|---|
| N/A | | N/A |
| **Business Address** | **City** | **State** / **Zip** |
| N/A | N/A | N/A / N/A |
| **Phone** | **Title** | **Number of Employed Hours** |
| N/A | N/A | N/A |
| **Description of Duties** | | |
| N/A | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state? | | ✔ |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline. | | ✔ |

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| N/A | N/A | N/A | N/A | N/A |
| **Case #** N/A | | **Governing, licensing, Arresting Presiding Body/Agency/Court** N/A | | |
| **Reason/Charge** N/A | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** N/A | | | **Lawsuit/Arbitration/Bankruptcy** N/A | |
| **Name of Business/Industry/Entity** N/A | | | | |

**Provide explanation below:**

N/A

Original Signature (electronic, copies or stamps not accepted)

6/29/2023
Date

I, BRITANY DAVIS, certify that as the MDEG Administrator for

PHOENIX ASSURANCE, LLC,

that I (initial that you have read and meet the following requirements):

1. BD Have a high school diploma or its equivalent;
2. BD Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. BD Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. BD Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

BRITANY DAVIS
Print Name (First, Last)

BD
Original Signature (electronic, copies or stamps not accepted)

6/29/2023
Date

| Board Use Only | Date Received: 7-3-23 |
|---|---|

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

# Designated Representative Application

Rev (05/12/2022)

**Section 1: Pharmacy/Wholesaler Information**

Name of Pharmacy/Wholesaler PHOENIX ASSURANCE, LLC

Pharmacy/Wholesaler License # (if applicable) N/A

Physical Address 4835 MENDENHALL ROAD SOUTH

City MEMPHIS State TN Zip 38141

Mailing Address (if different from physical address) 4750 PLEASANT HILL ROAD

City MEMPHIS State TN Zip 38118

Telephone 901-368-8940 Website WWW.PHOENIXASSURANCE3PL.COM

Licensing Company Email LICENSING4835@PA3PL.COM

**Section 2: Personal Information**

First BRITANY Middle JO Last DAVIS

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]DOUGLAS DRIVE

City OLIVE BRANCH State MS Zip 38654

Telephone 901-368-8967 Email BDAVIS@PA3PL.COM

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| UT MEMPHIS | | 08/99-05/00 | |
| **Address** | **City** | **State** | **Zip** |
| 920 MADISON AVE, SUITE 807 | MEMPHIS | TN | 38163 |
| **Diploma/Degree obtained, if any** | | | |
| N/A | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| UNION UNIVERSITY | | 08/95-05/99 | |
| **Address** | **City** | **State** | **Zip** |
| 1050 UNION UNIVERSITY DRIVE | JACKSON | TN | 38305 |
| **Diploma/Degree obtained, if any** | | | |
| BACHELOR OF SCIENCE | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| WESTVIEW HIGH SCHOOL | | | |
| **Address** | **City** | **State** | **Zip** |
| 8161 HIGHWAY 45 | MARTIN | TN | 38237 |
| **Diploma/Degree obtained, if any** | | | |
| HIGH SCHOOL DIPLOMA | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| N/A | | N/A | |
| **Address** | **City** | **State** | **Zip** |
| N/A | N/A | N/A | N/A |
| **Diploma/Degree obtained, if any** | | | |
| N/A | | | |
| **School Name** | | **From - To (MM/YY – MM/YY** | |
| N/A | | N/A | |
| **Address** | **City** | **State** | **Zip** |
| N/A | N/A | N/A | N/A |
| **Diploma/Degree obtained, if any** | | | |
| N/A | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 2011-PRESENT | [redacted]OUGLAS DRIVE | OLIVE BRANCH | MS | 38654 |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |
| N/A | N/A | N/A | N/A | N/A |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| PHOENIX ASSURANCE, LLC | | | 08/2019-PRESENT |
| **Business Address** | **City** | **State** | **Zip** |
| 4835 MENDENHALL ROAD SOUTH | MEMPHIS | TN | 38141 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| 901-368-8940 | DESIGNATED REPRESENTATIVE | 6,000+ | |
| **Description of Duties** | | | |
| DIRECT, CONTROL, AND IMPLEMENT ALL REGULATORY ACTIVITIES | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| N/A | | | N/A |
| **Business Address** | **City** | **State** | **Zip** |
| N/A | N/A | N/A | N/A |
| **Phone** | **Title** | **Number of Employed Hours** | |
| N/A | N/A | N/A | |
| **Description of Duties** | | | |
| N/A | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| N/A | | | N/A |
| **Business Address** | **City** | **State** | **Zip** |
| N/A | N/A | N/A | N/A |
| **Phone** | **Title** | **Number of Employed Hours** | |
| N/A | N/A | N/A | |
| **Description of Duties** | | | |
| N/A | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| N/A | | | N/A |
| **Business Address** | **City** | **State** | **Zip** |
| N/A | N/A | N/A | N/A |
| **Phone** | **Title** | **Number of Employed Hours** | |
| N/A | N/A | N/A | |
| **Description of Duties** | | | |
| N/A | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| N/A | | | N/A |
| **Business Address** | **City** | **State** | **Zip** |
| N/A | N/A | N/A | N/A |
| **Phone** | **Title** | **Number of Employed Hours** | |
| N/A | N/A | N/A | |
| **Description of Duties** | | | |
| N/A | | | |

Continue on next page if additional space is needed.

| Business Name | | From - To (MM/YY – MM/YY) |
|---|---|---|
| N/A | | N/A |
| **Business Address** | **City** | **State** / **Zip** |
| N/A | N/A | N/A / N/A |
| **Phone** | **Title** | **Number of Employed Hours** |
| N/A | N/A | N/A |
| **Description of Duties** | | |
| N/A | | |

| Business Name | | From - To (MM/YY – MM/YY) |
|---|---|---|
| N/A | | N/A |
| **Business Address** | **City** | **State** / **Zip** |
| N/A | N/A | N/A / N/A |
| **Phone** | **Title** | **Number of Employed Hours** |
| N/A | N/A | N/A |
| **Description of Duties** | | |
| N/A | | |

| Business Name | | From - To (MM/YY – MM/YY) |
|---|---|---|
| N/A | | N/A |
| **Business Address** | **City** | **State** / **Zip** |
| N/A | N/A | N/A / N/A |
| **Phone** | **Title** | **Number of Employed Hours** |
| N/A | N/A | N/A |
| **Description of Duties** | | |
| N/A | | |

| Business Name | | From - To (MM/YY – MM/YY) |
|---|---|---|
| N/A | | N/A |
| **Business Address** | **City** | **State** / **Zip** |
| N/A | N/A | N/A / N/A |
| **Phone** | **Title** | **Number of Employed Hours** |
| N/A | N/A | N/A |
| **Description of Duties** | | |
| N/A | | |

| Business Name | | From - To (MM/YY – MM/YY) |
|---|---|---|
| N/A | | N/A |
| **Business Address** | **City** | **State** / **Zip** |
| N/A | N/A | N/A / N/A |
| **Phone** | **Title** | **Number of Employed Hours** |
| N/A | N/A | N/A |
| **Description of Duties** | | |
| N/A | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a **copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # N/A. Provide all the following *where applicable*:

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| N/A | N/A | N/A | N/A | N/A |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| N/A | | N/A | | |
| **Reason/Charge** | | | | |
| N/A | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| N/A | | | N/A | |
| **Name of Business/Industry/Entity** | | | | |
| N/A | | | | |

**Provide explanation below:**

N/A

Original Signature (electronic, copies or stamps not accepted)

6/29/2023
Date

I, BRITANY DAVIS, certify that as the designated representative for

PHOENIX ASSURANCE, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. BD I am at least 21 years of age;
3. BD I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. BD I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. BD I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. BD I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. BD I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

BRITANY DAVIS
Print Name (First, Last)

BD
Original Signature (electronic, copies or stamps not accepted)

6/29/2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

BRITANY DAVIS
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/29/2023
Date

---

**Please have this section completed in the presence of a Notary Public.**

State of TENNESSEE, ss. County of SHELBY

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

6/29/2023
**Date**

Subscribed and Sworn to before me this 29th day of JUNE.

**Notary Public Signature**

LINNEA M HESS
STATE OF TENNESSEE
NOTARY PUBLIC
My Commission Expires on 02/07/2027
SHELBY COUNTY

**(Seal)**

PHOENIX ASSURANCE

05 April 2023

Phoenix Assurance, LLC
4835 Mendenhall Road South
Memphis, TN 38141

Please see below for a list of employees for Phoenix Assurance, 4835 Mendenhall Road South, Memphis, TN 38141.

- Hulesy Britt
- Rita Parks
- Charles Seagle II
- Jonathan Tabares
- Matthew Tanksley

**Phoenix Assurance, LLC**
**4835 Mendenhall Road South**
**Memphis, TN 38141**

License/Registrations/Permits List

| State | License# | Issued | Expires | Status |
|---|---|---|---|---|
| ARKANSAS | WD05783 | 12/06/2022 | 12/31/2024 | ACTIVE/NO DISCIPLINE |
| ARIZONA | L00043 | 01/30/2023 | 10/31/2024 | ACTIVE/ NO DISCIPLINE |
| CONNECTICUT | CSW.0005192 | 01/10/2023 | 06/30/2023 | ACTIVE/NO DISCIPLINE |
| INDIANA | 94000246A | 12/12/2022 | 09/30/2024 | ACTIVE/ NO DISCIPLINE |
| KANSAS | 23-119657 | 01/09/2023 | 06/30/2023 | ACTIVE/NO DISCIPLINE |
| KENTUCKY | TPL00426 | 08/01/2022 | 06/30/2023 | ACTIVE/ NO DISCIPLINE |
| MISSOURI | 2022049923 | 12/29/2022 | 10/31/2023 | ACTIVE/NO DISCIPLINE |
| NEW MEXICO | WD00013172 | 07/21/2022 | 12/31/2023 | ACTIVE/ NO DISCIPLINE |
| NORTH CAROLINA | 1695 | 0/25/2023 | 12/31/2023 | ACTIVE/ NO DISCIPLINE |
| OHIO | 0170000106 | 01/19/2023 | 06/30/2023 | ACTIVE/NO DISCIPLINE |
| OKLAHOMA | 88-L-7764 | 01/17/2023 | 01/31/2024 | ACTIVE/NO DISCIPLINE |
| OREGON | DDA-0000621 | 12/19/2022 | 09/30/2023 | ACTIVE/NO DISCIPLINE |
| TENNESSEE | 0000007973 | 06/09/2022 | 06/30/2024 | ACTIVE/ NO DISCIPLINE |
| TEXAS | 1003485 | 08/29/2022 | 07/06/2024 | ACTIVE/ NO DISCIPLINE |
| UTAH | 13166041-1714 | 12/15/2022 | 09/30/2025 | ACTIVE/ NO DISCIPLINE |
| WEST VIRGINIA | 3PL0000410 | 12/13/2022 | 06/30/2024 | ACTIVE/ NO DISCIPLINE |

QuVa PHARMA

# Attachment 1

3 Sugar Creek Center Blvd, Suite 250
Sugar Land, TX 77478

888.339.0874
QuVaPharma.com

QuVa PHARMA

# NAC 639.593 Section 7

7. Unless the Board otherwise requires, a wholesaler is not required to submit fingerprints pursuant to subsection 6 if:
   (a) The wholesaler's securities are publicly traded and regulated by the Securities Exchange Act of 1934, as amended, 15 U.S.C. §§ 78a et seq.;
   (b) The wholesaler is owned by a corporation whose securities are publicly traded and regulated by the Act;
   (c) The wholesaler is accredited by the National Association of Boards of Pharmacy under the Verified-Accredited Wholesale Distributors program;
   (d) The wholesaler is a manufacturer of prescription drugs; or
   (e) The wholesaler is a facility that distributes prescription drugs manufactured by a single manufacturer.

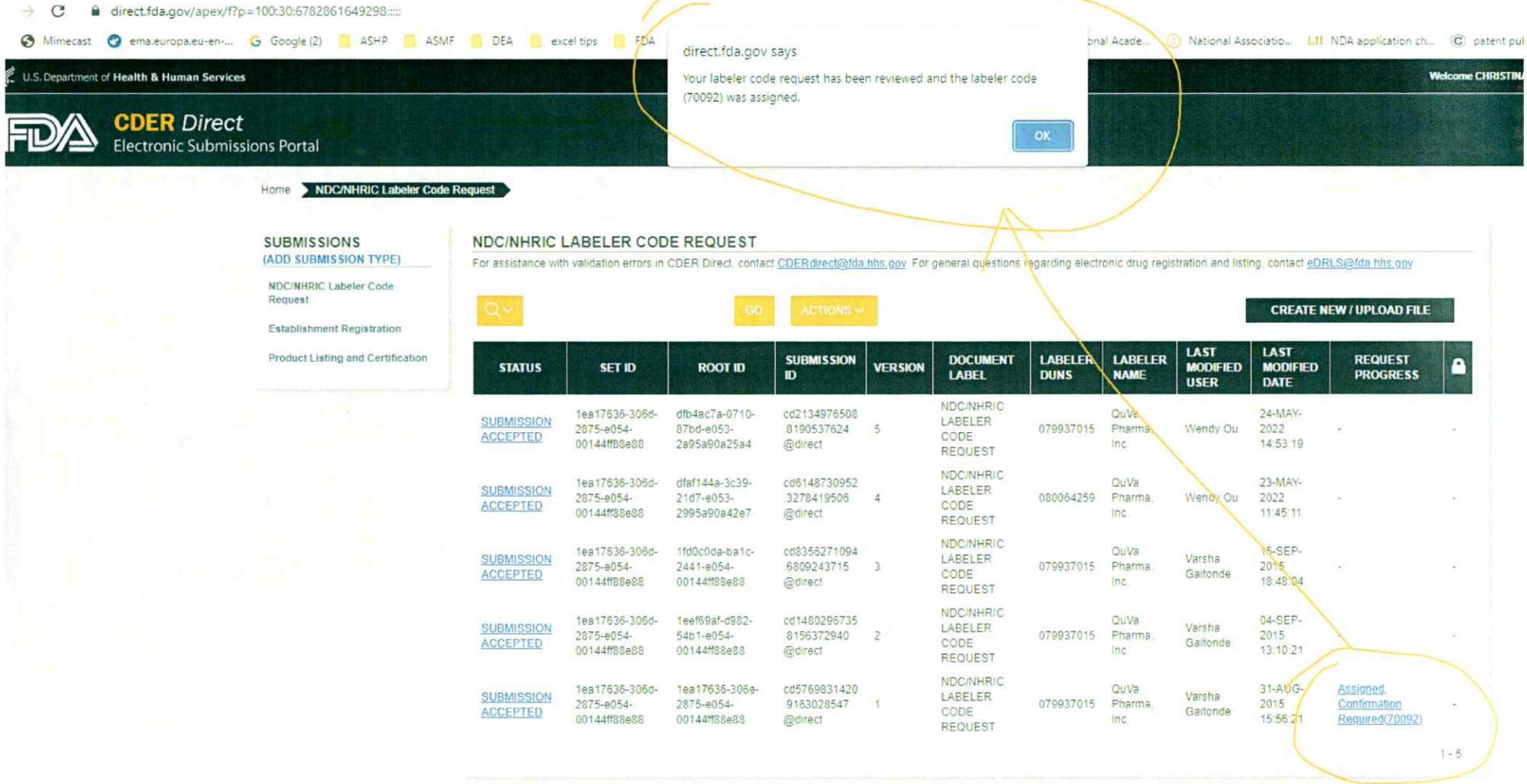
(Added to NAC by Bd. of Pharmacy, eff. 7-16-92; A by R013-01, 11-1-2001; R049-04, 2-28-2005; R218-05, 5-4-2006; R051-07, 12-4-2007)

QuVa PHARMA

# Attachment 2

3 Sugar Creek Center Blvd, Suite 250
Sugar Land, TX 77478

888.339.0874
QuVaPharma.com


direct.fda.gov/apex/f?p=100:30:6782861649298::::
direct.fda.gov says
Your labeler code request has been reviewed and the labeler code (70092) was assigned.
OK
U.S. Department of Health & Human Services
CDER Direct
Electronic Submissions Portal
Welcome CHRISTIN
Home
NDC/NHRIC Labeler Code Request
SUBMISSIONS
(ADD SUBMISSION TYPE)
NDC/NHRIC Labeler Code Request
Establishment Registration
Product Listing and Certification
NDC/NHRIC LABELER CODE REQUEST
For assistance with validation errors in CDER Direct, contact CDERdirect@fda.hhs.gov. For general questions regarding electronic drug registration and listing, contact eDRLS@fda.hhs.gov
GO
ACTIONS
CREATE NEW / UPLOAD FILE
STATUS
SET ID
ROOT ID
SUBMISSION ID
VERSION
DOCUMENT LABEL
LABELER DUNS
LABELER NAME
LAST MODIFIED USER
LAST MODIFIED DATE
REQUEST PROGRESS
SUBMISSION ACCEPTED
1ea17636-306d-2875-e054-00144ff88e88
dfb4ac7a-0710-87bd-e053-2a95a90a25a4
cd2134976508.8190537624@direct
5
NDC/NHRIC LABELER CODE REQUEST
079937015
QuVa Pharma, Inc.
Wendy Ou
24-MAY-2022 14:53:19
SUBMISSION ACCEPTED
1ea17636-306d-2875-e054-00144ff88e88
dfaf144a-3c39-21d7-e053-2995a90a42e7
cd6148730952.3278419506@direct
4
NDC/NHRIC LABELER CODE REQUEST
080064259
QuVa Pharma, Inc.
Wendy Ou
23-MAY-2022 11:45:11
SUBMISSION ACCEPTED
1ea17636-306d-2875-e054-00144ff88e88
1fd0c0da-ba1c-2441-e054-00144ff88e88
cd8356271094.6809243715@direct
3
NDC/NHRIC LABELER CODE REQUEST
079937015
QuVa Pharma, Inc.
Varsha Gaitonde
15-SEP-2015 18:48:04
SUBMISSION ACCEPTED
1ea17636-306d-2875-e054-00144ff88e88
1eef69af-d982-54b1-e054-00144ff88e88
cd1480296735.8156372940@direct
2
NDC/NHRIC LABELER CODE REQUEST
079937015
QuVa Pharma, Inc.
Varsha Gaitonde
04-SEP-2015 13:10:21
SUBMISSION ACCEPTED
1ea17636-306d-2875-e054-00144ff88e88
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cd5769831420.9163028547@direct
1
NDC/NHRIC LABELER CODE REQUEST
079937015
QuVa Pharma, Inc.
Varsha Gaitonde
31-AUG-2015 15:56:21
Assigned. Confirmation Required(70092)
1 - 5

# 4U

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application
## Non-Refundable $1,000 Fee

Rev (05/12/2022)

| Where is the facility located? | | ☐ Nevada ☑ Out-of-State |
|---|---|---|
| **Type of Application (check applicable box)** | | **Wholesaler Business Type (check applicable box)** |
| ☑ New Wholesaler<br>☐ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number: Pending; current MDEG license #: WH MP01409 | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: Respironics Logistics Services, LLC

Physical Address: 174 Tech Center Drive, Suite 200

City: Mt. Pleasant State: PA Zip: 15666

Mailing Address (if different from physical address): Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover State: MA Zip: 01810

Telephone: 724-387-5200 Website: www.philips.com

Name of Designated Representative (DR): Robert P. Mansberry

Licensing Company Email: beth.c.rogers@philips.com DR Email: robert.mansberry@philips.com

| **Entities the Wholesaler will Serve (✓ all applicable)** | **Products to be Handled or Wholesaled (✓ all applicable)** | **Type of Wholesaling (✓ all applicable)** |
|---|---|---|
| ☐ Pharmacies | ☐ Dangerous Drugs | ☐ Manufacturer |
| ☐ Practitioners | ☐ Controlled Substances | ☐ Repacker |
| ☑ Hospitals | ☑ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ☑ Wholesalers | ☐ Others: | ☐ Warehouse |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ☑ Others: DME Dealers and DME Distributors. | | ☑ Others: Own Label and Wholesale Distributor |

| **Section 2: History of Company** | **Yes** | **No** |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | X |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | X |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | X |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | X |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | X |

N/A

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # _____. **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| Reason/Charge | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| Name of Business/Industry/Entity | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

9-9-2022
Date

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: N/A - No pharmaceuticals products are handled or sold. See Attachment A.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

N/A

**Section 4: Publicly Traded Corporation**

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: Delaware

Parent Company (if any): Philips RS North America LLC

Corporation/Organization Name: Respironics Logistics Services, LLC

Mailing Address: Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover State: MA Zip: 01810

Telephone: 978-659-4884 Email: beth.c.rogers@philips.com

Contact Person Name: Beth C. Rogers

N/A

**Section 6: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A

**Section 7: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | X |
| N/A<br>1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | X | |
| 1. Copy of FDA registration See Attachment B<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment C | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** See Attachment D | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** N/A | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** See Attachment D | | ✓ | | |
| • **List of all partners and their percent ownership.** N/A | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment E | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment F | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - Wholly owned by parent company, Philips RS North America LLC. | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** N/A | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) N/A | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment D | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment G | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ See Attachment H | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). See Attachment I | ✓ | ✓ | ✓ | ✓ |
| N/A **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%207-1-19.pdf | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Respironics Logistics Services, LLC

Facility Name

Robert P. Mansberry

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

9-9-2022

Date

| Board Use Only | Date Received: 5-11-23 | Amount: 1000.00 CK-645 |
|---|---|---|

## Attachment A

## Nature of Business

Respironics Logistics Services, LLC (RILS) is a wholesale distributor of prescription and nonprescription medical devices for the diagnosis, treatment and monitoring of various medical conditions, including, but not limited to, sleep, respiratory, and cardiopulmonary disorders. RILS is a wholly-owned subsidiary of its parent company, Philips RS North America LLC. RILS distributes the parent company's products to customers (wholesalers, hospitals, durable medical equipment (DME) dealers, and distributors). All sales of these products are made by the manufacturer to its DME or homecare provider customers, and not to individual patients, but the items will be shipped directly to the DME or homecare provider's patient. The patient's DME or homecare provider provides medical supervision of the patient.

Currently, RILS ships replacement masks and other accessories (including headgear, tubing, filters, chinstraps, and humidifier chambers) for CPAP devices. No drugs, whether prescription or non-prescription, are distributed.

FDA

FDA Home[3] Medical Devices[4] Databases[5]

## Establishment Registration & Device Listing

New Search

Back To Search Results

**Establishment:**
RESPIRONICS, INC.
174 Tech Center Drive
Mount Pleasant, PA 15666
**Registration Number:** 3002797442
**FEI Number*:** 3002797442
**Status:** Active
**Initial Distributor/Importer:** Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
**Date Of Registration Status:** 2023

**Owner/Operator:**

Philips Medical Systems International BV[6]
Veenpluis 6
Best, NL 5684PC
**Owner/Operator Number:** 2518422[7]

**Official Correspondent:**
Tom Fallon
Philips
6501 Living Place
Pittsburgh, PA 15206
**Phone:** 978-9415572

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
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FDA

FDA Home[3] Medical Devices[4] Databases[5]

## Establishment Registration & Device Listing

New Search

Back To Search Results

**Establishment:**
RESPIRON CS, INC.
174 Tech Center Drive
Mount Pleasant, PA 15666
**Reg stration Number:** 3002797442
**FEI Number*:** 3002797442
**Status:** Act ve
**Initial Distributor/Importer:** Yes
*Note Firm May Have Add t ona Estab ishment Types.
P ease Rev ew List ngs For Further Informat on
**Date Of Registration Status:** 2022

**Owner/Operator:**

Ph ips Medical Systems Internationa BV[6]
Veenp uis 6
Best, NL 5684PC

**Owner/Operator Number:** 2518422[7]

**Officia Correspondent**
Tom Fa on
Ph ips
6501 Living Place
P ttsburgh, PA 15206
**Phone:** 978 9415572

* F rm Estab shment dentifier (FEI) shou d be used for dentificat on of ent ties within the mports message set

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6. /scr pts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&estab ishmentName=&Num=&StateName=&CountryName=&Reg strat onNumber=&OwnerOperatorNumber=2518422&OwnerOperator
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U.S. Food and Drug Admin stration
10903 New Hampshire Avenue
Si ver Spring, MD 20993
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7. /scr pts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&estab ishmentName=&Num=&StateName=&CountryName=&Reg strat onNumber=&OwnerOperatorNumber=2518422&OwnerOperator

**Attachment D**

**LLC Information**

Respironics Logistics Services, LLC

**Respironics Logistics Services, LLC is wholly-owned by its parent company, Philips RS North America LLC.**

**LLC Officers:**

David Ferguson
*President and Chief Executive Officer*

Paul Cavanaugh
*Vice President*

Ling Liu
*Vice President and Manager*

Joseph E. Innamorati
*Vice President, Secretary, and Manager*

Irma I. Gomez
*Assistant Secretary*

**Facility Manager:**

Robert P. Mansberry
*Operations Manager*

**Enclosed please find a list of site employees.**

**Attachment E**

**Delaware Certificate of Good Standing**

# Delaware

The First State



I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "RESPIRONICS LOGISTICS SERVICES, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FOURTEENTH DAY OF MARCH, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "RESPIRONICS LOGISTICS SERVICES, LLC" WAS FORMED ON THE TWENTIETH DAY OF AUGUST, A.D. 2007.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

4409766 8300

SR# 20230976722

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202907038

Date: 03-14-23

# Certificate of Registration

**Certificate No.** 6000008932
(A certificate starting with a number 4, 5 or 6 does not permit the posession or sale of controlled substances or prescription drugs.)

**Category:**

Devices

**Drug & Device Registration**
555 WALNUT ST
FORUM PLACE -7th FLOOR -SUITE 701
HARRISBURG, PA 17101
(717) 787-4779

RESPIRONICS LOGISTICS SERVICES, LLC
174 TECH CENTER DRIVE
SUITE 200
MT. PLEASANT, PA 15666

The above business is registered in the required category to conduct and maintain a facility in accordance with the provisions of the Controlled Substance, Drug, Device and Cosmetic Act #64, approved September 9, 1972.

Issuance Date: June 20, 2016
Expiration Date: The Last Day of August, 2023

Susan Coble
Deputy Secretary for Quality Assurance

pennsylvania
DEPARTMENT OF HEALTH

K Klinepeter
Keara Klinepeter
Acting Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

ACORD®

# CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
01/03/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

| | |
|---|---|
| PRODUCER<br>Marsh USA, Inc.<br>1166 Avenue of the Americas<br>New York, NY 10036<br><br>CN101736188-GAUW-NI-22-23 | CONTACT NAME:<br>PHONE (A/C, No, Ext):<br>FAX (A/C, No):<br>E-MAIL ADDRESS: |
| INSURED<br>Philips North America LLC<br>222 Jacobs Street, 3rd Floor<br>Cambridge, MA 02141 | INSURER(S) AFFORDING COVERAGE — NAIC #<br>INSURER A : National Union Fire Insurance Co Of Pittsburgh — 19445<br>INSURER B : Safety National Casualty Corp. — 15105<br>INSURER C :<br>INSURER D :<br>INSURER E :<br>INSURER F : |

**COVERAGES** **CERTIFICATE NUMBER:** NYC-011181363-12 **REVISION NUMBER:** 10

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

| INSR LTR | TYPE OF INSURANCE | ADDL INSD | SUBR WVD | POLICY NUMBER | POLICY EFF (MM/DD/YYYY) | POLICY EXP (MM/DD/YYYY) | LIMITS | | |
|---|---|---|---|---|---|---|---|---|---|
| A | COMMERCIAL GENERAL LIABILITY<br>CLAIMS-MADE [X] OCCUR<br>GEN'L AGGREGATE LIMIT APPLIES PER:<br>[X] POLICY [ ] PRO-JECT [ ] LOC<br>OTHER: | | | 536-18-48 | 12/31/2022 | 12/31/2023 | EACH OCCURRENCE<br>DAMAGE TO RENTED PREMISES (Ea occurrence)<br>MED EXP (Any one person)<br>PERSONAL & ADV INJURY<br>GENERAL AGGREGATE<br>PRODUCTS - COMP/OP AGG | $<br>$<br>$<br>$<br>$<br>$ | 2,000,000<br>500,000<br>10,000<br>2,000,000<br>5,000,000<br>5,000,000 |
| B | AUTOMOBILE LIABILITY<br>[X] ANY AUTO<br>OWNED AUTOS ONLY<br>HIRED AUTOS ONLY<br>SCHEDULED AUTOS<br>NON-OWNED AUTOS ONLY | | | CA6675481 | 12/31/2022 | 12/31/2023 | COMBINED SINGLE LIMIT (Ea accident)<br>BODILY INJURY (Per person)<br>BODILY INJURY (Per accident)<br>PROPERTY DAMAGE (Per accident) | $<br>$<br>$<br>$ | 2,000,000 |
| A | [X] UMBRELLA LIAB [X] OCCUR<br>EXCESS LIAB CLAIMS-MADE<br>DED RETENTION $ | | | 10-736-193 | 12/31/2022 | 12/31/2023 | EACH OCCURRENCE<br>AGGREGATE | $<br>$ | 5,000,000<br>5,000,000 |
| B<br>B | WORKERS COMPENSATION AND EMPLOYERS' LIABILITY<br>ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) [N] N/A<br>If yes, describe under DESCRIPTION OF OPERATIONS below | | | LDS4047559 (AOS)<br>PS4047560 (WI) | 12/31/2022<br>12/31/2022 | 12/31/2023<br>12/31/2023 | [X] PER STATUTE [ ] OTH-ER<br>E.L. EACH ACCIDENT<br>E.L. DISEASE - EA EMPLOYEE<br>E.L. DISEASE - POLICY LIMIT | $<br>$<br>$ | 2,000,000<br>2,000,000<br>2,000,000 |
| A | CYBER LIABILITY | | | 03-932-59-76<br>'Subject to a policy deductible' | 12/31/2022 | 12/31/2023 | Occurrence Limit<br>Aggregate Limit | | 10,000,000<br>10,000,000 |

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Additional Certificate Holder: Virginia Community College System Commonwealth of Virginia Virginia Community College System 147 Daleville Centre Drive Daleville, VA 24083.

Evidence of coverage.

**CERTIFICATE HOLDER**

Philips North America LLC
See above for the Complete Cert. Holder Name
222 Jacobs Street, 3rd Floor
Cambridge, MA 02141

**CANCELLATION**

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Marsh USA Inc.

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AGENCY CUSTOMER ID: CN101736188
LOC #: New York

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# ADDITIONAL REMARKS SCHEDULE



| AGENCY | NAMED INSURED |
|---|---|
| Marsh USA, Inc. | Philips North America LLC<br>222 Jacobs Street, 3rd Floor<br>Cambridge, MA 02141 |
| POLICY NUMBER | |
| CARRIER / NAIC CODE | EFFECTIVE DATE: |

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Named Insured Includes:
370 West Trimble Road LLC
AllParts Medical, LLC
BioTelemetry, Inc.
BioTel Research, LLC
BioTelemetry Care Management, LLC
Telcare Medical Supply, LLC
Telcare, LLC
Braemar Manufacturing, LLC
Cardiac Monitoring Holding Company, LLC
LifeWatch Corp.
LifeWatch Services, Inc.
Cardiologs Technologies Inc.
CardioNet, LLC
BioTel INR, LLC
Geneva Healthcare, LLC
VirtualScopics, LLC
Blue Willow Systems LLC
Discus Holdings, LLC
Discus Dental, LLC
Discus International, LLC
Discus Dental Canada, LLC
Electrical Geodesics LLC
Cerebral Data Systems, Inc. (CDS)
Intact Vascular, Inc.
Philips CS Corporation (formerly "Vita Topco, Inc." and "Philips Capsule Corporation")
Capsule Technologies, Inc.
CapsuleTech, Inc.
Philips Healthcare Informatics, Inc.
Philips Image Guided Therapy Corporation
Cardioprolific Inc.
Crux Biomedical, LLC
Spectranetics LLC
Volcano Atheromed, Inc.
Philips Medical Systems (Cleveland), Inc.
Philips Medical Systems MR, Inc.
Philips DS North America LLC
Philips North America, LLC
Philips North America, LLC D/B/A Philips Healthcare
Philips Oral Healthcare, LLC
Philips RS North America Holding Corporation
Philips RS North America LLC
Respironics California, LLC
Respironics Colorado, Inc.
Respironics Logistics Services, LLC
Respironics Novametrix, LLC
Philips Semiconductors Inc.
Remote Diagnostics Technologies LLC


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AGENCY CUSTOMER ID: CN101736188
LOC #: New York

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# ADDITIONAL REMARKS SCHEDULE



| AGENCY | NAMED INSURED |
|---|---|
| Marsh USA, Inc. | Philips North America LLC<br>222 Jacobs Street, 3rd Floor<br>Cambridge, MA 02141 |
| POLICY NUMBER | |
| CARRIER / NAIC CODE | EFFECTIVE DATE: |

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Respiratory Technologies, Inc.
Tomtec Corporation
TR Management Company, LLC
U.S. Philips Corporation
Vesper Medical, Inc.
VISICU, Inc.
VitalHealth Software Corp.
Wellcentive LLC (formerly "Wellcentive, Inc.")
Wellcentive QR, LLC
American Color & Chemical, L.L.C.
ATL Ultrasound, Inc.
Philips Ultrasound LLC (formerly "Philips Ultrasound, Inc.")
ATL International LLC
Philips Electronics North America Foundation
Philips Electronics Realty, LLC
Philips Medical Systems Export, Inc.
Philips MPEG Inc.
Philips Project Management, LLC


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**Respironics Logistics Services, LLC Employee List**

Anthony Orange
Brendan Jalosky
David Zofsak
Garrett Twardesky
Rita Thompson

## Attachment H

## Medical Devices, Equipment and Gases (MDEG) Administrator Form

# Robert P. Mansberry

[redacted] Rehoboth Church Road
Perryopolis, PA 15473
[redacted]

**Current Position:**
Respironics Logistics Services, LLC
*Operations Manager*
3/2021 - Present

Responsible for management of all personnel in Mount Pleasant Distribution Center. Oversee all operations and product flow. Inspection of materials/QC of product flow. Responsible for maintaining highest safety standards, and monthly audit reporting.

**Carlisle Construction Materials**
Smithfield, PA 15478
*Production*
*Production Supervisor*
2018- 3/2021

- Weekly, monthly reporting and audits
- Maintain highest standard of FPY and Utilization
- Assist in hiring, training, discipline, termination of workforce
- Scheduling and directing of workforce
- Inspection of materials for quality/defects
- Familiar with Lean concepts, 5S, SFIS, Gemba, Kaizen
- Outlook, Word, and Excel, SAP
- Champion IdeaGen and Employee Recognition Programs
- Work harmoniously with all levels of company personnel

**Eastman Chemical**
West Elizabeth, PA 15088
*Production*
*Skilled Labor*
2017-2019

- Trained on all aspects of safety for all tasks
- Forklift certified
- Able to perform multiple functions, on multiple units
- Sample batch products to ensure integrity of material
- Daily, weekly, monthly inventory / SAP
- Load, unload, handle hazardous chemicals

**Arcelor Mittal Steel**
Monessen, PA 15062
*Production*
*Skilled Labor*
2016-2017

- Trained on all aspects of safety for labor tasks
- Qualified on multiple labor grade positions
- Qualified and operate all battery equipment
- Work as a team to accomplish daily production quota

**Global Pump**
Brownsville, PA 15417
*Branch Manager,*
*Operations and Logistics*
*Skilled labor*
2014-2016

- Order, receive, reconcile all products/parts
- Establish parts room using KANBAN system of inventory
- Daily supervision of office and shop personnel
- Establish/maintain new and existing vendors/trucking accounts
- Communicate daily with Regional Account Manager and corporate personnel to establish lines of transportation between branches/jobsites
- Maintain jobsites, inventory, records for PA and MD branches
- Establish and implement safety procedures, office and yard policies
- Load / off load trucks by hand, fork truck, JLG
- Negotiate pricing/contracts
- Experience with Dedicated loads/LTL
- Integration of SAP

**U.S. Steel Corporation**
Clairton, Pa 15025
*Crew Leader*
*Production*
*Skilled Labor*
2005-2014

- Achieved new department safety record for days without incident
- Supervised crew on daily tasks to ensure consistent operations
- Oversaw and reconciled shipment information
- Communicated with multiple departments and companies to maintain flow of multiple jobs/tasks/materials
- Responsible for payroll and vacation scheduling
- Load railcars with conveyor /boom for shipment
- Experienced with diesel locomotive and 240v electric locos

**Education/Affiliations**

- VP - American Legion Riders, 2018
- OSHA 10 Certified, 2015
- Safe Land PEC Certified, 2014
- Certificate of Training, Class 5-98, Regimental Orientation Program, Fort Myer, VA, 1998
- Diploma, Class 47-97, Infantry School, 19th Infantry Regiment, Fort Benning, GA, 1997
- Diploma, McGuffey High School, Claysville, PA, 1995

**Qualifications**

- Reliable, result oriented professional with over 20 years management skills working with teams of 10+ personnel
- Selected for highly elite Army ceremonial unit (top 2% of the Army)
- Proven ability to motivate self and team members in accomplishing all assignments at above standard levels
- 20+ years of experience in customer relations.
- 16+ years of experience in an industrial atmosphere.
- Knowledge of SAP
- Over 9 years Logistics and Operations experience
- Efficiently/effectively perform duties and assignments under pressure
- Quickly and successfully adapt to new ideas and methods
- Confident in making independent decisions
- 7+ years working in rail yard/with railed equipment

References Available upon request

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of MDEG Respironics Logistics Services, LLC MDEG License # (if applicable) MP01409

Physical Address 174 Tech Center Drive, Suite 200

City Mt. Pleasant State PA Zip 15666

Mailing Address (if different from physical address) Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City Andover State MA Zip 01810

Telephone 724-387-5200 Website www.philips.com

Licensing Company Email beth.c.rogers@philips.com

**Section 2: Personal Information**

First Robert Middle Paul Last Mansberry

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City Andover State MA Zip 01810

Telephone [redacted] Email robert.mansberry@philips.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) Honorably discharged 09/2001 | X | |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | X |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| McGuffey High School | | 08/91 - 06/95 | |
| Address | City | State | Zip |
| 86 McGuffey Drive | Claysville | PA | 15323 |
| Diploma/Degree obtained, if any | | | |
| High School Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 03/22 - Present | [redacted] Barclay Street | Greensburg | PA | 15601 |
| 05/04 - 03/22 | [redacted] Rehoboth Church Road | Perryopolis | PA | 15473 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Respironics Logistics Services, LLC | | | 03/21 - Present | |
| Business Address | | City | State | Zip |
| 174 Tech Center Drive, Suite 200 | | Mt. Pleasant | PA | 15666 |
| Phone | Title | | Number of Employed Hours | |
| 724-387-5200 | Operations Manager | | 45 hours per week | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| | | | | |
| Phone | Title | | Number of Employed Hours | |
| | | | | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| | | | | |
| Phone | Title | | Number of Employed Hours | |
| | | | | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| | | | | |
| Phone | Title | | Number of Employed Hours | |
| | | | | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| | | | | |
| Phone | Title | | Number of Employed Hours | |
| | | | | |
| Description of Duties | | | | |

Continue on next page if additional space is needed.

N/A

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | X |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state? | | X |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline. | | X |

N/A

**Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # _____. **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| | | | | |
| Reason/Charge | | | | |
| | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| | | | | |
| Name of Business/Industry/Entity | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

9-9-2022
Date

I, Robert P. Mansberry, **certify that as the MDEG Administrator for**

Respironics Logistics Services, LLC,

**that I (initial that you have read and meet the following requirements):**

1. RPM Have a high school diploma or its equivalent;
2. RPM Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. RPM Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. RPM Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Robert Mansberry
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9-1-2022
Date

| Board Use Only | Date Received: 5-11-23 |
|---|---|

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

### Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Respironics Logistics Services, LLC

Pharmacy/Wholesaler License # (if applicable): Pending; current MDEG license #: MP01409

Physical Address: 174 Tech Center Drive, Suite 200

City: Mt. Pleasant State: PA Zip: 15666

Mailing Address (if different from physical address): Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover State: MA Zip: 01810

Telephone: 724-387-5200 Website: www.philips.com

Licensing Company Email: beth.c.rogers@philips.com

### Section 2: Personal Information

First: Robert Middle: Paul Last: Mansberry

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: Philips Healthcare, Attn: Beth C. Rogers, 3000 Minuteman Road

City: Andover State: MA Zip: 01810

Telephone: [redacted] Email: robert.mansberry@philips.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) Honorably discharged 09/2001 | X | |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | X |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| McGuffey High School | | 08/91 - 06/95 | |
| **Address** | **City** | **State** | **Zip** |
| 86 McGuffey Drive | Claysville | PA | 15323 |
| **Diploma/Degree obtained, if any** | | | |
| High School Diploma | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |
| **School Name** | | **From - To (MM/YY – MM/YY** | |
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 03/22 - Present | [redacted] Barclay Street, Greensburg, PA 15601 | Greensburg | PA | 15601 |
| 05/04 - 03/22 | [redacted] Rehoboth Church Road | Perryopolis | PA | 15473 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| | | | |
|---|---|---|---|
| Business Name: Respironics Logistics Services, LLC | | | From - To (MM/YY – MM/YY): 03/21 - Present |
| Business Address: 174 Tech Center Drive, Suite 200 | City: Mt. Pleasant | State: PA | Zip: 15666 |
| Phone: 724-387-5200 | Title: Operations Manager | | Number of Employed Hours: 45 hours per week |
| Description of Duties: | | | |

| | | | |
|---|---|---|---|
| Business Name: | | | From - To (MM/YY – MM/YY): |
| Business Address: | City: | State: | Zip: |
| Phone: | Title: | | Number of Employed Hours: |
| Description of Duties: | | | |

| | | | |
|---|---|---|---|
| Business Name: | | | From - To (MM/YY – MM/YY): |
| Business Address: | City: | State: | Zip: |
| Phone: | Title: | | Number of Employed Hours: |
| Description of Duties: | | | |

| | | | |
|---|---|---|---|
| Business Name: | | | From - To (MM/YY – MM/YY): |
| Business Address: | City: | State: | Zip: |
| Phone: | Title: | | Number of Employed Hours: |
| Description of Duties: | | | |

| | | | |
|---|---|---|---|
| Business Name: | | | From - To (MM/YY – MM/YY): |
| Business Address: | City: | State: | Zip: |
| Phone: | Title: | | Number of Employed Hours: |
| Description of Duties: | | | |

Continue on next page if additional space is needed.

N/A

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | X |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | N/A | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | X |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | X |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | X |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | X |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | X |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | X |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | X |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | X |

N/A

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # _____. **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| | | | | |
| Reason/Charge | | | | |
| | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| | | | | |
| Name of Business/Industry/Entity | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

9-9-2022
Date

I, Robert P. Mansberry, **certify that as the designated representative for**

Respironics Logistics Services, LLC,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Robert Mansberry
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9-9-2022
Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Robert Mansberry
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9-9-22
Date

---

**Please have this section completed in the presence of a Notary Public.**

State of PENNSYLVANIA, ss. County of WESTMORELAND

I, ROBERT P. MANSBERRY, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

9-9-2022
**Date**

Subscribed and Sworn to before me this 9 day of Sept 2022

**Notary Public Signature**

Commonwealth of Pennsylvania - Notary Seal
Michelle L. Kwasny, Notary Public
Westmoreland County
My commission expires December 6, 2023
Commission number 1238412
Member, Pennsylvania Association of Notaries
(Seal)

# NEVADA STATE BOARD OF PHARMACY

**985 Damonte Ranch Pkwy Suite 206**
**Reno, NV 89521**
**(775) 850-1440**
**Fax: (775) 850-1444**

## PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 30185503

Application/License No. _____

*See attached list of principal names (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is *See attached list of principal addresses (Address of Applicant/Principal), as PRINCIPAL, and Western Surety Company (Surety Company), a corporation organized under the laws of the state of South Dakota (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 151 N Franklin Street Chicago, IL 60606 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 21, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 21st day of April, 20 23.

APPLICANT/PRINCIPAL

**See attached principal signature page

Authorized Representative

SURETY COMPANY

Western Surety Company

Surety Company's Representative

Kristin S. Bender, Attorney-in-fact
print name

Nevada Non-Resident Producer License No. 829075

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Jessica Iannotta

Witness April D. Perez

Countersigned by:

N/A
Nevada Resident Agent

# Western Surety Company

## POWER OF ATTORNEY APPOINTING INDIVIDUAL ATTORNEY-IN-FACT

**Know All Men By These Presents,** That WESTERN SURETY COMPANY, a South Dakota corporation, is a duly organized and existing corporation having its principal office in the City of Sioux Falls, and State of South Dakota, and that it does by virtue of the signature and seal herein affixed hereby make, constitute and appoint Kristin S. Bender

, Individually

of Morristown, New Jersey, its true and lawful Attorney(s)-in-Fact with full power and authority hereby conferred to sign, seal and execute for and on its behalf bonds, undertakings and other obligatory instruments of similar nature

**- In Unlimited Amounts -**

Surety Bond Number: 30185503
Principal: See attached list of principals
Obligee: State of Nevada and Nevada State Board of Pharmacy

and to bind it thereby as fully and to the same extent as if such instruments were signed by a duly authorized officer of the corporation and all the acts of said Attorney, pursuant to the authority hereby given, are hereby ratified and confirmed.

This Power of Attorney is made and executed pursuant to and by authority of the By-Law printed on the reverse hereof, duly adopted, as indicated, by the shareholders of the corporation.

**In Witness Whereof,** WESTERN SURETY COMPANY has caused these presents to be signed by its Vice President and its corporate seal to be hereto affixed on this 2nd day of February, 2021.

WESTERN SURETY COMPANY

Paul T. Bruflat

Paul T. Bruflat, Vice President

State of South Dakota }
County of Minnehaha } ss

On this 2nd day of February, 2021, before me personally came Paul T. Bruflat, to me known, who, being by me duly sworn, did depose and say: that he resides in the City of Sioux Falls, State of South Dakota; that he is the Vice President of WESTERN SURETY COMPANY described in and which executed the above instrument; that he knows the seal of said corporation; that the seal affixed to the said instrument is such corporate seal; that it was so affixed pursuant to authority given by the Board of Directors of said corporation and that he signed his name thereto pursuant to like authority, and acknowledges same to be the act and deed of said corporation.

My commission expires
March 2, 2026

M. BENT
NOTARY PUBLIC
SOUTH DAKOTA

M. Bent

M. Bent, Notary Public

**CERTIFICATE**

I, L. Nelson, Assistant Secretary of WESTERN SURETY COMPANY do hereby certify that the Power of Attorney hereinabove set forth is still in force, and further certify that the By-Law of the corporation printed on the reverse hereof is still in force. In testimony whereof I have hereunto subscribed my name and affixed the seal of the said corporation this 21 day of April, 2023.

WESTERN SURETY COMPANY

L. Nelson

L. Nelson, Assistant Secretary

Form F4280-2-2021

**Authorizing By-Law**

# ADOPTED BY THE SHAREHOLDERS OF WESTERN SURETY COMPANY

This Power of Attorney is made and executed pursuant to and by authority of the following By-Law duly adopted by the shareholders of the Company.

Section 7. All bonds, policies, undertakings, Powers of Attorney, or other obligations of the corporation shall be executed in the corporate name of the Company by the President, Secretary, and Assistant Secretary, Treasurer, or any Vice President, or by such other officers as the Board of Directors may authorize. The President, any Vice President, Secretary, any Assistant Secretary, or the Treasurer may appoint Attorneys in Fact or agents who shall have authority to issue bonds, policies, or undertakings in the name of the Company. The corporate seal is not necessary for the validity of any bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation. The signature of any such officer and the corporate seal may be printed by facsimile.

# WESTERN SURETY COMPANY
## Sioux Falls, South Dakota
## Statement of Net Admitted Assets and Liabilities
## December 31, 2021

### ASSETS

| | | |
|---|---|---|
| Bonds | $ | 1,940,298,870 |
| Stocks | | 19,721,943 |
| Cash, cash equivalents, and short-term investments | | 32,146,891 |
| Receivables for securities | | 140,000 |
| Investment income due and accrued | | 17,433,547 |
| Premiums and considerations | | 54,366,110 |
| Amounts recoverable from reinsurers | | 3,204,634 |
| Current federal and foreign income tax recoverable and interest thereon | | - |
| Net deferred tax asset | | 14,565,007 |
| Receivable from parent, subsidiaries, and affiliates | | 14,891,869 |
| Other assets | | 1,037 |
| Total Assets | $ | 2,096,769,908 |

### LIABILITIES AND SURPLUS

| | | |
|---|---|---|
| Losses | $ | 214,859,103 |
| Loss adjustment expense | | 48,667,258 |
| Commissions payable, contingent commissions and other similar charges | | 10,885,216 |
| Other expenses (excluding taxes, license and fees | | - |
| Taxes, License and fees (excluding federal and foreign income taxes) | | 2,781,662 |
| Federal and foreign income taxes payable | | 300,285 |
| Unearned premiums | | 263,317,295 |
| Advance premiums | | 6,618,279 |
| Ceded reinsurance premiums payable (net of ceding commissions) | | 5,081,348 |
| Amounts withheld or retained by company for account of other | | 10,237,011 |
| Provision for reinsurance | | 6,261,560 |
| Payable to parent, subsidiaries and affiliates | | 7,170 |
| Payable on security transactions | | 35,226 |
| Other liabilities | | 155,189 |
| Total Liabilities | $ | 569,206,602 |

| | | | |
|---|---|---|---|
| Surplus Account: | | | |
| Common stock | $ 4,000,000 | | |
| Gross paid in and contributed surplus | 286,896,195 | | |
| Unassigned funds | 1,236,667,111 | | |
| Surplus as regards policyholders | | $ | 1,527,563,306 |
| Total Liabilities and Capital | | $ | 2,096,769,908 |

I, Julie Lee, Assistant Vice President of Western Surety Company hereby certify that the above is an accurate representation of the financial statement of the Company dated December 31, 2021, as filed with the various Insurance Departments and is a true and correct statement of the condition of Western Surety Company as of that date.

WESTERN SURETY COMPANY

By Julie Lee
Assistant Vice President, External Reporting

Subscribed and sworn to me this 14th day of March, 2022.

My commission expires:

"OFFICIAL SEAL"
CHRISTOPHER LOPATOWSKI
Notary Public, State of Illinois
My Commission Expires 01/14/2024

By Christopher Lopatowski
Notary Public

**APPLICANT/PRINCIPALS:**

AllParts Medical, LLC, 400 Brick Church Park Drive, Nashville, TN 37207
Discus Dental, LLC, 1700 A South Baker Ave., Ontario, CA 91761
Philips Healthcare Informatics, Inc., 4430 Rosewood Drive, Suite 200, Pleasanton, CA 94588
Philips Healthcare, a division of Philips North America LLC, 22100 Bothell Everett Hwy, Bothell, WA 98021
Philips Healthcare, a division of Philips North America LLC, 222 Jacobs Street, Cambridge, MA 02141 Philips Ultrasound LLC, 22100 Bothell Everett Highway, Bothell, WA 98021
Philips Image Guided Therapy Corporation, 3721 Valley Center Drive, Suite 500, San Diego, CA 92130
Philips Image Guided Therapy Corporation, 2451 Mercantile Drive, Rancho Cordova, CA 95742
Respironics Logistics Services, LLC, 174 Tech Center Drive, Suite 200, Mt. Pleasant, PA 15666
Spectranetics LLC, 9965 Federal Drive, Colorado Springs, CO 80921
Visicu, Inc., 217 E. Redwood Street, Suite 1900, Baltimore, MD 21202

Authorized Representative - [redacted] Paul Cavanaugh

Witness

Witness

Philips RS North America LLC, 1010 Murry Ridge Lane, Murrysville, PA 15668
Philips RS North America LLC, 174 Tech Center Drive, Suite 100, Mt. Pleasant, PA 15666

Authorized Representative - Stuart Cashman

Witness

Witness

Philips RS North America LLC LIMITED LIABILITY COMPANY SEAL 1984 DELAWARE

DISCUS DENTAL LIMITED LIABILITY SEAL 2007 CALIFORNIA COMPANY LLC

PHILIPS NORTH AMERICA LLC LIMITED LIABILITY SEAL 1987 DELAWARE COMPANY

PHILIPS ULTRASOUND LLC LIMITED LIABILITY SEAL 1973 WASHINGTON COMPANY

SPECTRANETICS LLC LIMITED LIABILITY SEAL 1988 DELAWARE COMPANY

IMAGE GUIDED THE SEAL 2000 DELAWARE

# 4V

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

**Non-Refundable $1,000 Fee**

Rev (08/17/2022)

| Where is the facility located? | ☐ Nevada ■ Out-of-State |
|---|---|

| Type of Application (check applicable box) | | Wholesaler Business Type (check applicable box) |
|---|---|---|
| ■ New Wholesaler | * If making a change, provide current license number: | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) |
| ☐ Ownership Change* | | ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) |
| ☐ Name Change* | | ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) |
| ☐ Location Change* (in-state only) | WH N/A | ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: UPS Supply Chain Solutions, Inc.

Physical Address: 11991 Landon Drive

City: Mira Loma State: CA Zip: 91752

Mailing Address (if different from physical address): **same as physical address**

City: State: Zip:

Telephone: 951-749-3310 Website: www.ups.com

Name of Designated Representative (DR): Marissa Aispuro

Licensing Company Email: ralicensing@ups.com DR Email: maispuro@ups.com

| Entities the Wholesaler will Serve (✓ all applicable) | Products to be Handled or Wholesaled (✓ all applicable) | Type of Wholesaling (✓ all applicable) |
|---|---|---|
| ■ Pharmacies | ■ Dangerous Drugs | ☐ Manufacturer |
| ■ Practitioners | ☐ Controlled Substances | ☐ Repacker |
| ■ Hospitals | ■ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ■ Wholesalers | ■ Others: Prescription Human & Veterinary drugs<br>Over the Counter (OTC) Human & Veterinary drugs | ☐ Warehouse |
| ■ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ☐ Others: | | ■ Others: 3PL |

| Section 2: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✔ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | ✔ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | ✔ | |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✔ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # 3 . Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** see attachment# 1 | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

25 JUL 2023
Date

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: Medtronic
Address: 710 Medtronic Parkway City: Minneapolis State: MN Zip: 55432

Name: Avid Bio Services, Inc.
Address: 14191 Myford Road City: Tustin State: CA Zip: 92780

Name: Gilead
Address: 5200 Illumina Way City: San Diego State: CA Zip: 92122

Name: Watmind
Address: 4780 I-55 North Frontage Road, Suite 450 City: Jackson State: MS Zip: 39211

**Section 4: Publicly Traded Corporation**

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address: N/A
City: State: Zip:
Telephone: Email:
Contact Person Name:

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

28-Jul-2023

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: Delaware
Parent Company (if any): United Parcel Service of America, Inc.
Corporation/Organization Name: UPS Supply Chain Solutions, Inc.
Mailing Address: 12380 Morris Road
City: Alpharetta State: GA Zip: 30005
Telephone: 678-746-4100 Email: ralicensing@ups.com
Contact Person Name: Felix X. Chang

**Section 6: Partnership**

Partnership Name:
Mailing Address:
City: N/A State: Zip:
Telephone: Email:
Contact Person Name:

28-Jul-2023

**Section 7: Sole Owner**

Owner's Name:
Business Name: N/A
Business Address:
City: State: Zip:
Telephone: Email:

28-Jul-2023

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: see attachment# 2 | | ✔ |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. see attachment# 3 | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | | ✔ |
| 1. Copy of FDA registration N/A<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. N/A | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** see attachment# 4 | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** N/A | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** see attachment# 5 | | ✓ | | |
| • **List of all partners and their percent ownership.** N/A | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** see attachment# 6 | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ Enclosed | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** N/A | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) N/A | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** see attachment# 7 | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** see attachment# 8 | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ Enclosed | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). see attachment# 9 | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: N/A http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. N/A | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

UPS Supply Chain Solutions, Inc.

Facility Name

Nolys Reyes

Print Name of Authorized Person Submitting Application

Nolys Reyes

Original signature of Authorized Person (copies or stamps not accepted)

25 Jul 2023

Date

| Board Use Only | Date Received: 7/31/23 | Amount: 1000-CK-1110877 |
|---|---|---|

Attachment# 1

# Disciplinary Statement
# UPS Supply Chain Solutions, Inc. ("UPS SCS")

## WHOLESALE LICENSE

## Matters Related to Colorado Order
## 1645 Satellite Blvd, Duluth, GA

*Final*

As previously disclosed by UPS Supply Chain Solution, Inc. (UPS SCS), to your agency in 2010, the Colorado Board of Pharmacy's Stipulation and Final Agency Order ("Colorado Order") was effective October 18, 2010, with regard to UPS SCS's Duluth, GA facility's Colorado Out-of-State Wholesaler License # WHO-7462. UPS SCS's Duluth facility did not file Colorado's required notice of change of Designated Representative within Colorado's required 14-day timeframe to file such notice. UPS SCS implemented corrective actions and has successfully completed the terms of the Colorado order. Please note, UPS SCS's Colorado Out-of-State Wholesaler License # WHO-7462 was not and is not restricted, modified, revoked or limited in any way. UPS SCS has a copy of the Colorado Case No. 2011-000273 documentation related to the Colorado Order on file with the UPS SCS Regulatory Affairs Department.

*Final*

On November 15, 2011, UPS SCS informed your agency of the Iowa Board of Pharmacy's (IBoP) action concerning Iowa Wholesale Drug License #5820 and which became effective November 11, 2011. This Iowa Stipulation and Consent Order (the "Iowa Order") relates to the Colorado Order and the untimely filing of notice regarding the Colorado Order to the IBoP. UPS SCS has successfully completed the terms of the Iowa Order and Iowa Wholesale Drug License #5820 has not and is not restricted, modified, revoked or limited in any way. UPS SCS has a copy of the Iowa Case No. 2010-162 documentation on file with the UPS SCS Regulatory Affairs Department. Note: This Iowa matter is a spin-off of the Colorado matter summarized above. It is based on the same underlying facts that gave rise to the Colorado matter. It is **not** based on an independent set of facts.

*Final*

On October 18, 2013, UPS SCS informed your agency of the Consent Order and Stipulation between the Michigan Board of Pharmacy (BOP) and UPS SCS based on the underlying Colorado matter summarized above, which was executed by the Michigan BOP on October 9, 2013 (the "Michigan Order"). As previously disclosed to you, pursuant to this Consent Order, UPS SCS paid a fine of two thousand five hundred dollars. The Consent Order and Stipulation specifically provided that "no patient safety issues were involved," and the BOP did not impose any other penalty. UPS SCS's Michigan licenses have not been restricted, modified, revoked, or limited in any way. Note: The Michigan Order is directly related to the Colorado matter summarized above. It is based on the same underlying facts that gave rise to the Colorado matter. It is not based on an independent set of facts.

**PHARMACY LICENSE**

**Matters Related to Kentucky Agreed Orders**
**1860 Outer Loop Road, Louisville, KY**

*Final*

UPS SCS dispenses medical devices, including diabetes-related pumps, to consumers from its Kentucky licensed pharmacy facility. Not all states recognize the Durable Medical Equipment or Home Medical Equipment provider category for entities that dispense medical devices rather than drugs. Those states that do not recognize these categories require a non-resident or out of state pharmacy permit for dispensing medical devices. Accordingly, UPS SCS obtained a home-state pharmacy permit in Kentucky and numerous non-resident pharmacy permits and DME/HME permits in other states. On September 12, 2012, the Kentucky Board of Pharmacy ("KYBoP") and UPS SCS executed final Agreed Orders relating to minor violations under Kentucky Administrative Regulations 2:270 and Kentucky Revised Statutes Sec. 315.121(6) in connection with late filing of pharmacy technician registrations at UPS SCS's Louisville, Kentucky facility (the "Kentucky Orders"). UPS SCS and the KYBoP agreed to address the Kentucky Orders informally by entering in the aforementioned Agreed Orders in lieu of the KYBoP filing a formal complaint. UPS SCS self-reported this action to your agency on September 18, 2012. UPS SCS takes this and all regulatory matters seriously and has implemented corrective action. Moreover, UPS SCS has instituted internal safeguards to ensure that applicable regulatory compliance is maintained in the future. UPS SCS's Kentucky pharmacy license (Kentucky Pharmacy License #P07277) remains current and in good standing and was not and has not been restricted, modified, revoked, or limited in any way.

*Final*

On May 14, 2013, UPS SCS informed your agency of the Texas Board of Pharmacy's (TXBoP) action concerning UPS SCS Texas Class E Nonresident Pharmacy License #26160 and which became effective May 7, 2013. As already disclosed to you, on May 14, 2013, the Texas Board of Pharmacy (TXBoP) and UPS SCS executed a final Agreed Board Order (the "Texas Order") relating to the above-mentioned Kentucky Pharmacy License Agreed Orders. Pursuant to the Texas Agreed Board Order, the TXBoP reprimanded UPS SCS's Nonresident Pharmacy License. The Texas Board of Pharmacy did not levy a fine or any other penalty on the License. The License was not and is not restricted, modified, revoked or limited in any way. UPS SCS has a copy of the Texas Agreed Board Order # L-13-004 on file with the UPS SCS Regulatory Affairs Department. Note: The Texas Order is directly related to the Kentucky pharmacy license matter summarized above. It is based on the same underlying facts that gave rise to the Kentucky matter. It is **not** based on an independent set of facts.

*Final*

On April 22, 2014, UPS SCS informed your agency of the Consent Order and Stipulation between the Michigan Board of Pharmacy (BOP) and UPS SCS based on the Kentucky Order summarized above, which was adopted by the Michigan BOP on April 9, 2014 (the "Michigan Order"). As previously disclosed to you, pursuant to this Consent Order, UPS SCS paid a fine of two hundred fifty dollars. The Consent Order and Stipulation specifically provided that "no patient safety issues were involved," and the BOP did not impose any other penalty. UPS SCS's Michigan licenses have not been restricted, modified, revoked, or limited in any way. Note: The Michigan Order is directly related to the Kentucky matter summarized above. It is based on the same underlying facts that gave rise to the Kentucky matter. It is not based on an independent set of facts.

**BEFORE THE STATE BOARD OF PHARMACY**

**STATE OF COLORADO**

**Case No. 2011-000273**

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**STIPULATION AND FINAL AGENCY ORDER**

---

IN THE MATTER OF DISCIPLINARY PROCEEDING REGARDING THE NON-RESIDENT PRESCRIPTION DRUG WHOLESALER REGISTRATION OF UPS SUPPLY CHAIN SOLUTIONS, INC., REGISTRATION NO. WHO-7462,

Respondent.

---

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and UPS Supply Chain Solutions, Inc. ("Respondent") to resolve all matters pertaining to Board Case Number 2011-000273, as follows:

## FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent, its registration as a non-resident prescription drug wholesaler, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of the Pharmaceuticals and Pharmacists Act at Title 12, Article 22, C.R.S.

2. Respondent was originally registered as an non-resident prescription drug wholesaler in the State of Colorado on December 8, 2008, being issued registration number WHO-7462, and has been so registered at all times relevant to this disciplinary action.

3. Respondent does not contest these findings and hereby waives any further proof in this proceeding before the Board regarding the following findings.

4. Respondent failed to timely submit an application to the Board detailing a change in designated representative and fee. In this case, forty-six (46) days transpired between the date the previous designated representative ceased the position and the date the application and fee were received.

5. Respondent states and affirms that it was never without the proper oversight of a designated representative but failed to timely submit the change application to the Board because of human error. Further, Respondent states and affirms that it has identified the cause of the error and has implemented corrective actions.

6. Respondent does not contest that the conduct described above constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

**12-22-125. Unprofessional conduct - grounds for discipline.**

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(I) Any of the provisions of this part 1, including but not limited to any acts in section 12-22-126;

(II) The lawful rules of the board; or

(III) Any state or federal law pertaining to drug.

**12-22-802. Wholesaler license requirements**

(2)(b) An applicant for a license shall pay any reasonable fee required by the accreditation body or the board and comply with any rules promulgated by the board;

(3) (VII) The name of the applicant's designated representative for the facility, the fingerprints of the designated representative, and a personal information statement for the designated representative that includes information as required by the board, including but not limited to the information in subsection (5) of this section; and

(5)(i) Update all of the information required in this part 8 whenever changes occur.

**Regulation 15.01.11 Minimum required information for registration.**

a. The following minimum information shall be required from each wholesaler as part of the registration:

(8) The name of the applicant's designated representative, who must meet the following requirements:

(a) Be at least twenty-one years of age;

(b) Have at least three years of full-time employment history with a pharmacy or a wholesaler in a capacity related to the dispensing and distribution of and the recordkeeping related to prescription drugs;

(c) Be employed by the applicant in a full-time managerial position;

(d) Be actively involved in and aware of the actual daily operation of the wholesaler;

(e) Be physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized, including, but not limited to, sick leave and vacation leave;

(f) Serve in the capacity of a designated representative for only one applicant or wholesaler at a time, except where more than one licensed wholesaler is co-located in the same facility and the wholesalers are members of an affiliated group as defined by section 1504 of the federal "Internal Revenue code of 1986."

(g) Not have any convictions under federal, state, or local law relating to wholesale or retail prescription drug distribution or controlled substances;

(h) Not have an felony convictions pursuant to federal, state, or local law; and

(i) Undergo a background check as required by CRS 12-22-803. And

(9) Wholesalers that distribute animal drugs exclusively are exempt from the requirements of 15.01.11(a)(8).

(b) Changes in any information in section 15.01.11 shall be submitted to the Colorado Board of Pharmacy within fourteen calendar days thereof.

**Regulation 15.01.14 Change of name, location, or ownership, or designated representative**

c. Any change in the designated representative of a wholesaler shall be reported to the board on a form supplied by the board within 14 calendar days of such change. The incoming designated representative must undergo the required background check.

7. The Board finds and concludes, and Respondent agrees, that based upon the above-described violations of the Pharmaceuticals and Pharmacists Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances.

## TERMS OF DISCIPLINE

8. **Fine with Surcharge.** Pursuant to §12-22-125.2(5), C.R.S., Respondent shall pay a fine of Five Thousand Dollars and No Cents ($5,000.00). Respondent understands and acknowledges that, pursuant to §24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall impose an additional surcharge of 10% of this fine. Respondent shall therefore pay a total amount of Five Thousand Five Hundred Dollars and No Cents ($5,500.00). The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent submits this signed Final Agency Order to the Board.

9. **Compliance.** Respondent shall submit all future applications detailing a change in designated representative and fee to the Board within fourteen (14) days of the previous designated representative ceasing the position.

10. **Other Requirements.** Respondent acknowledges and agrees that, as a condition of this Final Agency Order, Respondent shall:

a. promptly pay all Respondent's own fees and costs associated with this Final Agency Order;

b. comply fully with this Final Agency Order; and

c. comply fully with the Pharmacists and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

11. **Advisements and Waivers.** Respondent enters into this Final Agency Order freely and voluntarily, whether or not Respondent has consulted with legal counsel. Respondent acknowledges its understanding that it has the following rights:

a. to have formal notice of hearing and charges served upon it;

b. to respond to said formal notice of charges;

c. to have a formal disciplinary hearing pursuant to Sections 12-22-125 and 12-22-125.2(2)(a), C.R.S.; and

d. to appeal this Final Agency Order.

Respondent freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent to the sanctions imposed herein.

12. **Acknowledgments.** Respondent has read this Final Agency Order in its entirety and acknowledges, whether or not Respondent has consulted with legal counsel, that Respondent understands its legal consequences and agrees that none of its terms or conditions are unconscionable. Respondent is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent further acknowledges that it is not entering into this Final Agency Order under any duress.

13. **Violations.** Time is of the essence in this Final Agency Order. It is the responsibility of Respondent to take all appropriate steps to comply fully with this Final Agency Order. Respondent acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under §12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent's registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent to comply with all terms and conditions of this Final Agency Order.

14. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

15. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

16. **Effective Date.** This Final Agency Order shall become effective upon signature by a Board representative.

## ACCEPTED AND AGREED BY

**Respondent**

_____ Dated: 10/1/10
Authorized Representative / Title

Subscribed and sworn to before me in the County of Fulton, State of Georgia, this 1 day of October, 2010 by Daniel Silvernale, authorized representative of UPS Supply Chain Solutions, Inc.

My commission expires: Sept 21, 2013

DALE BANKS NOTARY PUBLIC FULTON COUNTY, GEORGIA MY COMMISSION EXPIRES SEPT 21 2013

Notary Public

## FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 18th day of October, 2010.

**State Board of Pharmacy**

BY: Wendy Anderson
Wendy Anderson
Program Director

## CERTIFICATE OF MAILING

This is to certify that I have duly mailed the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 29th day of September 2010, addressed as follows:

UPS Supply Chain Solutions, Inc.
Attn: Joy Roberts
1645 Satelite Blvd.
Duluth, GA 30097
(via email: joyroberts@ups.com)

/s/ John Steele
John C. Steele

## CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 18th day of October 2010, addressed as follows:

UPS Supply Chain Solutions, Inc.
Attn: Joy Roberts
1645 Satelite Blvd.
Duluth, GA 30097

Catie Kangiesser
Agent of the Board

**BEFORE THE IOWA BOARD OF PHARMACY**

| | | |
|---|---|---|
| Re:<br>Wholesale Drug License of<br>**UPS SUPPLY CHAIN SOLUTIONS, L.L.C.,**<br>License No. 5820<br>Respondent | )<br>)<br>)<br>)<br>)<br>) | Case No. 2010-162<br><br>**STIPULATION AND CONSENT ORDER** |

Pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2011), The Iowa Board of Pharmacy (hereinafter, the "Board") and UPS Supply Chain Solutions, L.L.C. (hereinafter, "Respondent"), have agreed to settle a contested case currently on file with the Board. The Statement of Charges filed against Respondent on September 13, 2011, and the licensee disciplinary proceeding related to the charges shall be resolved without a hearing, as the Board and Respondent have agreed to the following Stipulation and Consent Order:

1. Respondent's license to operate a wholesale drug business was renewed November 19, 2010, as evidenced by Wholesale Drug License Number 5820, recorded in the permanent records of the Board.

2. Wholesale Drug License Number 5820 issued to and held by Respondent is current and in force until December 31, 2011.

3. The Board has jurisdiction over the parties and the subject matter herein.

4. A Statement of Charges was filed against Respondent on September 13, 2011. The Statement of Charges alleges Respondent violated the pharmacy laws of the State of Colorado and failed to timely report the violation to the Board.

5. The records of the investigation indicate that Respondent has successfully

**RECEIVED**
OCT 28 2011
IOWA BOARD OF PHARMACY

completed the terms of the Colorado Stipulation and Final Agency Order.

6. Respondent has chosen not to contest the allegations set forth in the Statement of Charges and acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline described herein.

7. Upon the Board's approval of this Stipulation and Consent Order, Respondent shall be assessed a civil penalty in the amount of $1000. The civil penalty payment shall be made by check, payable to the Treasurer of Iowa and mailed to the executive director of the Board within 10 days after Respondent's receipt of notice of the Board's approval of this Stipulation and Consent Order. All civil penalty payments shall be deposited into the State of Iowa general fund. Upon the Board's receipt of the civil penalty, this disciplinary proceeding shall be concluded without further order of the Board.

8. The Board does not mandate any further corrective action.

9. Respondent agrees to obey all federal and state laws, rules, and regulations substantially related to the operation of a wholesale drug business.

10. Should Respondent violate or fail to comply with any of the terms or conditions of this Stipulation and Consent Order, the Board may initiate action to revoke or suspend Respondent's Iowa license to operate a wholesale drug business or to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A (2011), and 657 Iowa Administrative Code § 36.1.

11. This Stipulation and Consent Order is the resolution of a contested case. By entering into this stipulation, Respondent waives all rights to a contested case

hearing on the allegations contained in the Statement of Charges, and waives any objections to this Stipulation and Consent Order.

12. This Stipulation and Consent Order is a proposed settlement subject to approval by a majority of the full Board. If the Board fails to approve this Stipulation and Consent Order, it shall be of no force or effect to either party. If the Board approves this Stipulation and Consent Order, it shall be the full and final resolution of this matter.

13. The Board's approval of this Stipulation and Consent Order shall constitute a FINAL ORDER of the Board in a disciplinary action.

This Stipulation and Consent Order is voluntarily submitted by UPS Supply Chain Solutions, L.L.C., to the Iowa Board of Pharmacy for its consideration on this 31st day of October 2011.

UPS SUPPLY CHAIN SOLUTIONS, L.L.C.,
Respondent
By DANIEL SILVERNALE, Vice President, Finance and Healthcare Compliance

Subscribed and sworn to before me by Daniel Silvernale, who has stated to me that he is the VP, Finance, Healthcare Compliance of UPS Supply Chain Solutions, L.L.C., and is authorized to sign this Stipulation and Consent Order on behalf of UPS Supply Chain Solutions, L.L.C., on this 31st day of October 2011.

LINDA P BOWDEN NOTARY PUBLIC FULTON COUNTY, GEORGIA MY COMMISSION EXPIRES AUGUST 30, 2015

Linda P. Bowden
NOTARY PUBLIC IN AND FOR THE STATE OF GEORGIA

This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy on this 11th day of November 2011.

SUSAN FREY, Chairperson
Iowa Board of Pharmacy
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

cc: Scott M. Galenbeck
Assistant Attorney General
Office of the Attorney General
Hoover State Office Building
Des Moines, Iowa 50319

UPS Supply-settle 9-11.doc

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

UPS SUPPLY CHAIN SOLUTIONS INC.
License Numbers: 53-06-002764
53-15-027264

File Number: 53-10-118763
CONSENT ORDER AND STIPULATION

CONSENT ORDER

WHEREAS, an Administrative Complaint, hereafter Complaint, was issued on September 23, 2011, charging UPS Supply Chain Solutions Inc., hereafter Respondent Wholesaler, with having violated section 17768(2)(d) of the Public Health Code, 1978 PA 368, as amended; MCL 333.1101 et seq; and

WHEREAS, Respondent Wholesaler neither admits nor denies the facts alleged in the Complaint dated September 23, 2011, but agrees that the Disciplinary Subcommittee of the Michigan Board of Pharmacy, hereafter Disciplinary Subcommittee, shall treat the allegations as true, which finding shall have the same force and effect for purposes of this Consent Order as if evidence and arguments were presented in support of the allegations; and

WHEREAS, the Disciplinary Subcommittee reviewed the Stipulation and, based upon the matters asserted therein, agrees that the public interest is best served by resolution of the outstanding Complaint; now, therefore,

IT IS HEREBY FOUND that the facts alleged in the Complaint are true for the purposes of this Consent Order and constitute a violation of section 17768(2)(d) of the Public Health Code, supra.

Accordingly,

IT IS HEREBY ORDERED that for the cited violation of the Public Health Code, Respondent Wholesaler is FINED in the amount of $2,500.00 to be paid to the State of Michigan within 60 days of the effective date of this Order.

IT IS FURTHER ORDERED that the fine shall be mailed to the **Department of Licensing and Regulatory Affairs, Bureau of Health Care Services, Sanction Monitoring, P.O. Box 30189, Lansing, MI 48909**. The fine shall be paid by check or money order, made payable to the State of Michigan, and the check or money order shall clearly display file number **53-10-118763.**

IT IS FURTHER ORDERED that in the event Respondent violates any provision of this Order, the Disciplinary Subcommittee may proceed to take disciplinary action pursuant to 1996 AACS, R338.1632 and section 16221(h) of the Public Health Code, supra.

CONTINUED ON NEXT PAGE

IT IS FURTHER ORDERED that this Order shall be effective 30 days from the date signed by the Disciplinary Subcommittee, as set forth below.

Dated: 10/9/13

MICHIGAN BOARD OF PHARMACY

By _____
Chairperson, Disciplinary Subcommittee

## STIPULATION

1. Respondent Wholesaler neither admits nor denies the facts alleged in the Complaint dated September 23, 2011, but agrees that the Disciplinary Subcommittee shall treat the allegations as true, which finding shall have the same force and effect for purposes of this Consent Order as if evidence and arguments were presented in support thereof.

2. Respondent Wholesaler understands and intends that by signing this Stipulation, Respondent Wholesaler is waiving the right, pursuant to the Public Health Code, the rules promulgated thereunder, and the Administrative Procedures Act of 1969, 1969 PA 306, as amended; MCL 24.201 et seq, to require the Department of Licensing and Regulatory Affairs, hereafter Department, to prove the charges set forth in the Complaint by presentation of evidence and legal authority, and Respondent Wholesaler is waiving the right to appear with an attorney and such witnesses as Respondent Wholesaler may desire to present a defense to said charges.

3. Factors taken into consideration in the formulation of the within Consent Order are as follows:

> Subsequent to the adverse actions, Respondent Wholesaler submitted information about steps implemented by Respondent Wholesaler, in the state of Colorado, to ensure that this type of action will not recur, including establishing strategy groups and tactical teams which ensure regulations are met and all locations are compliant. Respondent Wholesaler indicated that a single manager coordinates the local teams to ensure all information is consistently distributed. No patient safety issues were involved in Respondent Wholesaler's actions.
>
> Respondent Wholesaler was cooperative in resolution of this matter. Respondent Wholesaler has been licensed in the state of Michigan since 2008 and has no other complaints against its license.

4. Patricia A. Smeelink, R.Ph., a member of the Michigan Board of Pharmacy who supports this proposal, and the Department's representative are both free to discuss this matter with the Disciplinary Subcommittee and recommend acceptance of the resolution set forth in the foregoing Consent Order.

5. The foregoing Consent Order is approved as to form and substance by Respondent Wholesaler and the Department and may be entered as the final order of the Disciplinary Subcommittee in said cause.

CONTINUED ON NEXT PAGE

6. This proposal is conditioned upon acceptance by the Disciplinary Subcommittee, Respondent Wholesaler and the Department expressly reserving the right to further proceedings without prejudice should the Consent Order be rejected.

AGREED TO BY:

Carole H. Engle, Director
Bureau of Health Care Services
Department of Licensing and
Regulatory Affairs

Dated: 8-7-13

AGREED TO BY:

Daniel Silvernale, Vice President
Authorized Representative for
UPS Supply Chain Solutions Inc.
Respondent Wholesaler

Dated: 6/28/13

Approved as to form by:

Max R. Hoffman, Jr.
Attorney for Respondent Wholesaler (P67550)

This is the last page of a Consent Order and Stipulation in the matter of UPS Supply Chain Solutions Inc., File Number 53-10-118763, before the Disciplinary Subcommittee of the Michigan Board of Pharmacy, consisting of five pages, this page included.

BH/PB

**COMMONWEALTH OF KENTUCKY**
**KENTUCKY BOARD OF PHARMACY**
**Case No. 11-0062A**

IN RE: PHARMACY PERMIT NO. P07277 HELD BY UPS SUPPLY CHAIN SOLUTIONS, INC.

***AGREED ORDER***

Come the parties, the Kentucky Board of Pharmacy ("the Board") and UPS Supply Chain Solutions, Inc. ("Respondent"), and both having been fully informed regarding the matter set forth herein, state as follows:

(1) Respondent is a pharmacy in the Commonwealth of Kentucky, having been assigned pharmacy permit no. P07277.

(2) (a) An investigation of Respondent's pharmacy revealed that numerous technicians worked on various dates in 2010, without being timely registered with the Board. The Respondent assured the technicians that it would take care of ensuring they were properly registered. Respondent subsequently properly registered the technicians. Nonetheless, the Respondent was in violation of KRS 315.121(1)(g).
(b) The technicians that worked without being appropriately registered with the Board were: Chelsea Hutchins, Alisha Netherton, Brittany Barger, Lauren Fisher, Karen Millay, Meghan Rae Yates, Michelle Green, Amanda Gracie, Faith Joway, Taylor Parker, Manoj Bhandari, Jonathan Pruitt, Whitney Wilson, Dustin R. Harris, Fabrice Mboya, Lauren Howell, Coco Boards, Benjamin Bickett, Jessica Horlander, Jason Cope, William Robert Bennett Jr, Thomas Hicks, Nimo Muhumed Mohamud, Harold Keith Newcom, Rodrick G Parrish, Johnathan Borho, Antoya Blackburn, Jonathan Graves, and Leilani Roach.
(c) The above facts subject Respondent to discipline pursuant to KRS 315.121(1) (h).

(3) Respondent takes compliance with KRS 315 seriously and as part of its corporate compliance program presented to the Board a detailed corrective action plan intended to ensure on-going compliance with KRS 315.121(1)(g).

(4) This matter is considered a violation pursuant to KRS 315.121(6) and 201 KAR 2:270.

(5) The Board and Respondent have agreed to address this matter informally by

entering into this Agreed Order, in lieu of the Board filing a formal Complaint.

WHEREFORE, IT IS HEREBY AGREED AND ORDERED THAT:

(A) Respondent shall be fined $2900.00 ($100 per technician) payable by September 5, 2012. Respondent's check shall be made payable to the Kentucky State Treasurer and sent to the Kentucky Board of Pharmacy, State Office Bldg., Annex, Ste. 300, 125 Holmes St., Frankfort, Kentucky 40601.

(B) By entering into this Agreed Order, Respondent expressly acknowledges that Respondent was fully and completely informed of Respondent's right to due process, that Respondent fully understands those rights, and that Respondent knowingly, voluntarily, and willingly agrees to waive those rights and to enter into this Agreed Order.

(C) The above information shall be reported to the National Association of Boards of Pharmacy ("NABP"), and is subject to disclosure under the Kentucky Open Records Act.

Joel Thornbury, President
Kentucky Board of Pharmacy

9/12/12
Date

UPS Supply Chain Solutions, Inc.
Respondent

8/14/12
Date

**COMMONWEALTH OF KENTUCKY**
**KENTUCKY BOARD OF PHARMACY**
**Case No. 11-0061A**

KY BOARD OF PHARMACY
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IN RE: PHARMACY PERMIT NO. P07277 HELD BY UPS SUPPLY CHAIN SOLUTIONS INC.

***AGREED ORDER***

Come the parties, the Kentucky Board of Pharmacy ("the Board") and UPS Supply Chain Solutions Inc. ("Respondent"), and both having been fully informed regarding the matter set forth herein, state as follows:

(1) Respondent is a pharmacy in the Commonwealth of Kentucky, having been assigned pharmacy permit no. P07277.

(2) (a) An investigation of Respondent's pharmacy revealed that Sherry Rich worked as a pharmacy technician from April 1, 2010 through November 19, 2010, without being timely registered with the Board. The Respondent assured Ms. Rich that it would take care of ensuring she was properly registered. Respondent subsequently properly registered Ms. Rich with the Board. Nonetheless, the Respondent was in violation of KRS 315.121(1)(g).

(b) The above facts subject Respondent to discipline pursuant to KRS 315.121(1) (h).

(3) Respondent takes compliance with KRS 315 seriously and as part of its corporate compliance program presented to the Board a detailed corrective action plan intended to ensure on-going compliance with KRS 315.121(1)(g).

(4) This matter is considered a violation pursuant to KRS 315.121(6) and 201 KAR 2:270.

(5) The Board and Respondent have agreed to address this matter informally by entering into this Agreed Order, in lieu of the filing of a formal Complaint.

WHEREFORE, IT IS HEREBY AGREED AND ORDERED THAT:

(A) Respondent shall be fined $125.00 payable by September 5, 2012. Respondent's check shall be made payable to the Kentucky State Treasurer and sent to the Kentucky

Board of Pharmacy, State Office Bldg., Annex, Ste. 300, 125 Holmes St., Frankfort, Kentucky 40601.

(B) By entering into this Agreed Order, Respondent expressly acknowledges that Respondent was fully and completely informed of Respondent's right to due process, that Respondent fully understands those rights, and that Respondent knowingly, voluntarily, and willingly agrees to waive those rights and to enter into this Agreed Order.

(C) The above information shall be reported to the National Association of Boards of Pharmacy ("NABP"), and is subject to disclosure under the Kentucky Open Records Act.

Joel Thornbury, President
Kentucky Board of Pharmacy

8/12/12
Date

UPS Supply Chain Solutions Inc.
Respondent

8/14/12
Date

*AGREED BOARD ORDER #L-13-004*

RE: IN THE MATTER OF
UPS SUPPLY CHAIN SOLUTIONS, INC.
(CLASS E NONRESIDENT
PHARMACY LICENSE #26160)

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy ("Board") the matter of Class E nonresident pharmacy license number 26160 issued to UPS Supply Chain Solutions, Inc. ("Respondent"), 1860 Outer Loop Road, Louisville, Kentucky 40219.

On September 8, 2012, Respondent self-reported to the Board the entry of two Agreed Orders by the Kentucky Board of Pharmacy, as described below in Counts (1) and (2).

By letter dated February 22, 2013, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

> Section 565.002 (a)(13); and Section 565.002(c) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2011), as alleged in the Counts below.

The conduct described in the Kentucky Board of Pharmacy's Agreed Orders is substantially similar to conduct described in:

> Section 565.002(a)(3); and Section 568.002(a) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2011); and
>
> Section 297.3(a)(1) of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2012).

**COUNTS**

(1) On or about September 12, 2012, the Kentucky Board of Pharmacy entered an Agreed Order in case number 11-0061A against the Kentucky pharmacy permit number P07277 held by UPS Supply Chain Solutions, Inc. The Order was based on allegations that from April through November of 2010, the pharmacy allowed an unregistered individual to perform duties of a pharmacy technician without being registered with the Kentucky Board of Pharmacy. The Order imposed an administrative penalty of $125.

(2) On or about September 12, 2012, the Kentucky Board of Pharmacy entered an Agreed Order in case number 11-0062A against the Kentucky pharmacy permit number P07277 held by UPS Supply Chain Solutions, Inc. The Order was based on allegations that, on various dates in 2010, the pharmacy allowed twenty-nine (29) unregistered individuals to

perform duties of a pharmacy technician without being registered with the Kentucky Board of Pharmacy. The Order imposed an administrative penalty of $2900.

An informal conference was held in the office of the Texas State Board of Pharmacy on April 2, 2013. Phillip Vowels, R.Ph., Pharmacist-in-Charge of Respondent; Sue Young, Director, Global Healthcare Compliance, for Respondent; Amy Carney, Regulatory Affairs Manager, for Respondent; Maureen O'Brien, Senior Quality Assurance Manager, for Respondent; Emily Johnson, Legal Counsel for Respondent; Hannah Heck, Legal Counsel for Respondent; and Michelle Williams, Legal Counsel for Respondent, appeared via teleconference. The informal conference was heard by a Board panel comprised of: Jeanne D. Waggener, R.Ph., Board Member; Gay Dodson, R.Ph., Executive Director/Secretary; and Carol Fisher, R.Ph., M.P.A., Director of Enforcement; with Kerstin E. Arnold, General Counsel. Stacy E. Martyak, Staff Attorney, was also in attendance.

By signing this Order, Daniel Silvernale, Vice President, for and on behalf of Respondent, neither admits nor denies the truth of the matters previously set out in this Order, and agrees that the Board has jurisdiction in this matter and waives the right to notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

## ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that Respondent's license is hereby reprimanded.

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 7th day of May, 2013.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Gay Dodson, R.Ph., Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Daniel Silvernale, Vice President of UPS Supply Chain Solutions, Inc.

APPROVED AS TO FORM:

Kerstin B. Arnold, General Counsel
Texas State Board of Pharmacy

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

UPS SUPPLY CHAIN SOLUTIONS INC.
License Number: 53-01-008968

File Number: 53-13-129412
CONSENT ORDER AND STIPULATION

## CONSENT ORDER

WHEREAS, an Administrative Complaint, hereafter Complaint, was issued on September 27, 2013, charging UPS Supply Chain Solutions Inc., hereafter Respondent Pharmacy, with having violated section 17768(2)(d) of the Public Health Code, 1978 PA 368, as amended; MCL 333.1101 et seq; and

WHEREAS, Respondent neither admits nor denies the facts alleged in the Complaint dated September 27, 2013, but agrees that the Disciplinary Subcommittee of the Michigan Board of Pharmacy, hereafter Disciplinary Subcommittee, shall treat the allegations as true, which finding shall have the same force and effect for purposes of this Consent Order as if evidence and argument were presented in support of the allegations; and

WHEREAS, the Disciplinary Subcommittee has reviewed the Stipulation and, based upon the matters asserted therein, agrees that the public interest is best served by resolution of the outstanding Complaint; now, therefore,

IT IS HEREBY FOUND that the facts alleged in the Complaint are true, for purposes of this Consent Order, and constitute a violation of section 17768(2)(d) of the Public Health Code, supra.

Accordingly, IT IS HEREBY ORDERED, that for the cited violation of the Public Health Code, Respondent Pharmacy is REPRIMANDED.

IT IS FURTHER ORDERED that for the cited violation of the Public Health Code, Respondent Pharmacy is FINED in the amount of $250.00 to be paid to the State of Michigan within 60 days of the effective date of this Order.

IT IS FURTHER ORDERED that the fine shall be mailed to the **Department of Licensing and Regulatory Affairs, Enforcement Division, Sanction Monitoring, P.O. Box 30189, Lansing, MI 48909.** The fine shall be paid by check or money order made payable to the state of Michigan, and the check or money order shall clearly display the file number **53-13-129412.**

IT IS FURTHER ORDERED that in the event Respondent Pharmacy violates any provision of this Order, the Disciplinary Subcommittee may proceed to take disciplinary action pursuant to 1996 AACS, R 338.1632 and section 16221(h) of the Public Health Code, supra.

CONTINUED ON NEXT PAGE

IT IS FURTHER ORDERED that this Order shall be effective 30 days from the date signed by the Disciplinary Subcommittee, as set forth below.

Dated: 4/9/14

MICHIGAN BOARD OF PHARMACY

By: _____
Chairperson, Disciplinary Subcommittee

STIPULATION

1. Respondent Pharmacy neither admits nor denies the facts alleged in the Complaint dated September 27, 2013, but agrees that the Disciplinary Subcommittee shall treat the allegations as true, which finding shall have the same force and effect for purposes of this Consent Order as if evidence and arguments were presented in support thereof.

2. Respondent Pharmacy understands and intends that by signing this Stipulation Respondent Pharmacy is waiving the right, pursuant to the Public Health Code, the rules promulgated thereunder, and the Administrative Procedures Act of 1969, 1969 PA 306, as amended; MCL 24.201 et seq, to require the Department of Licensing and Regulatory Affairs, hereafter Department, to prove the charges set forth in the Complaint by presentation of evidence and legal authority, and Respondent Pharmacy is waiving the right to appear with an attorney and such witnesses as Respondent Pharmacy may desire to present a defense to the charges.

3. Factors taken into consideration in the formulation of the within Consent Order are as follows:

> Respondent Pharmacy acknowledges the Kentucky Board of Pharmacy disciplinary action which precipitated the Complaint.

4. Harvey Schmidt, R.Ph., a member of the Michigan Board of Pharmacy who supports this proposal, and the Department's representative are both free to discuss this matter with the Disciplinary Subcommittee and recommend acceptance of the resolution set forth in this Consent Order.

5. The foregoing Consent Order is approved as to form and substance by Respondent Pharmacy and the Department and may be entered as the final order of the Disciplinary Subcommittee in this cause.

CONTINUED ON NEXT PAGE

6. The foregoing proposal is conditioned upon acceptance by the Disciplinary Subcommittee, Respondent Pharmacy and the Department expressly reserving the right to further proceedings without prejudice should the Consent Order be rejected.

AGREED TO BY:

Carole H. Engle, Director
Bureau of Health Care Services
Department Licensing and
Regulatory Affairs

Dated: 1-29-14

AGREED TO BY:

UPS Supply Chain Solutions Inc.
Respondent

Dated: 1/21/14

This is the final page of a Consent Order and Stipulation in the matter of UPS Supply Chain Solutions Inc., File Number 53-13-129412, before the Disciplinary Subcommittee of the Michigan Board of Pharmacy, consisting of five pages, this page included.

PB

**UPS Supply Chain Solutions, Inc.**
**12380 Morris Road**
**Alpharetta, GA 30005**
**Phone ~ (678) 746 4100**
**State of Incorporation: Delaware**
**Date of Incorporation: 8/29/88**
**FEIN ~ 94-3083515**

| Name/Title | Work Address | Work Phone | Work Fax | Email |
|---|---|---|---|---|
| **John Bolla**<br>**President** | 12380 Morris Road<br>Alpharetta, GA 30005 | (919) 455-8564 | (678) 746-8650 | jbolla@ups.com |
| **Stephen Hydrick**<br>**Vice President** | 12380 Morris Road<br>Alpharetta, GA 30005 | (678) 746-4404 | (678) 746-8650 | shydrick@ups.com |
| **Felix Chang**<br>**Vice President** | 12380 Morris Road<br>Alpharetta, GA 30005 | (678) 746-3452 | (678) 746-8650 | fxchang@ups.com |
| **Seth Bruckner**<br>**Vice President** | 12380 Morris Road<br>Alpharetta, GA 30005 | (678) 746-7413 | (678) 746-8650 | sbruckner@ups.com |
| **William M. Jacques**<br>**Vice President** | 12380 Morris Road<br>Alpharetta, GA 30005 | (678) 746-8718 | (678) 746-8650 | wjacques@ups.com |

**Parent Company Information:**
United Parcel Service of America, Inc.
55 Glenlake Parkway NE
Atlanta, GA 30328
P ~ (404) 828 6022
FEIN ~ 95-1732075
State/Date of Incorporation ~ DE 5/9/30

Attachment# 5

# Organizational Chart

## UPS SUPPLY CHAIN SOLUTIONS, INC.




THIS REPORT IS SUBMITTED IN CONFIDENCE AND APPLICABLE EXEMPTIONS TO THE FREEDOM OF INFORMATION ACT ARE TO BE INVOKED TO WITHHOLD IT FROM PUBLIC DISCLOSURE

Attachment# 6

# State Of Delaware

Entity Details

5/31/2023 1:56:19PM

File Number: 2170882
Entity Name: UPS SUPPLY CHAIN SOLUTIONS, INC.
Entity Kind: Corporation
Residency: Domestic
Status: Good Standing

Incorporation Date / Formation Date: 8/29/1988
Entity Type: General
State: DELAWARE
Status Date: 8/29/1988

**Registered Agent Information**

Name: CORPORATION SERVICE COMPANY
Address: 251 LITTLE FALLS DRIVE
City: WILMINGTON
State: DE
Phone: 302-636-5401

Country:
Postal Code: 19808

Attachment# 8

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

Renewal License

# Third-Party Logistics Provider

LICENSE NO. TPL 1315
RECEIPT NO. 00180375

VALID UNTIL SEPTEMBER 01, 2023

UPS SUPPLY CHAIN SOLUTIONS, INC
11991 LANDON DR
MIRA LOMA CA 91752

In accordance with the provisions of section 4160 of the Business and Professions Code, the firm name hereon is issued a Third-Party Logistics Provider License.

This license is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer(s) shareholder (more than 10 percent share change), manager, or responsible manager.

This permit is valid only at the address shown.

/07/22
/07/22 The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

FORM WPHTPL (09/30/19) TPL

ACORD®

# CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
5/15/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

| | |
|---|---|
| **PRODUCER**<br>Liberty Mutual Insurance Co. Nat'l Ins Northeast<br>500 N 3rd St, Suite 300<br>Wausau, WI 54403<br><br>www.LibertyMutual.com | **CONTACT NAME:**<br>**PHONE (A/C, No, Ext):** **FAX (A/C, No):**<br>**E-MAIL ADDRESS:** CMeCertProduction@LibertyMutual.com |
| **INSURED**<br>UPS SUPPLY CHAIN SOLUTIONS, INC.<br>12380 MORRIS ROAD<br>ALPHARETTA GA 30005 | **INSURER(S) AFFORDING COVERAGE** — **NAIC #**<br>**INSURER A :** Liberty Mutual Fire Insurance Company — 23035<br>**INSURER B :** LM Insurance Corporation — 33600<br>**INSURER C :** Liberty Insurance Corporation — 42404<br>**INSURER D :**<br>**INSURER E :**<br>**INSURER F :** |

**COVERAGES** **CERTIFICATE NUMBER:** 74387002 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

| INSR LTR | TYPE OF INSURANCE | ADDL INSD | SUBR WVD | POLICY NUMBER | POLICY EFF (MM/DD/YYYY) | POLICY EXP (MM/DD/YYYY) | LIMITS | |
|---|---|---|---|---|---|---|---|---|
| A<br>A<br>B | ✓ **COMMERCIAL GENERAL LIABILITY**<br>CLAIMS-MADE ✓ OCCUR<br>GEN'L AGGREGATE LIMIT APPLIES PER:<br>✓ POLICY PRO-JECT LOC<br>OTHER: | | | TB2-C21-095741-143<br>TB2-C21-095741-133<br>TB5-C21-095741-153 | 1/1/2023<br>1/1/2023<br>1/1/2023 | 1/1/2024<br>1/1/2024<br>1/1/2024 | EACH OCCURRENCE<br>DAMAGE TO RENTED PREMISES (Ea occurrence)<br>MED EXP (Any one person)<br>PERSONAL & ADV INJURY<br>GENERAL AGGREGATE<br>PRODUCTS - COMP/OP AGG | $ 1,000,000<br>$<br>$<br>$ 1,000,000<br>$ 1,000,000<br>$ 1,000,000 |
| A<br>A<br>A<br>B | **AUTOMOBILE LIABILITY**<br>✓ ANY AUTO<br>OWNED AUTOS ONLY<br>HIRED AUTOS ONLY<br>SCHEDULED AUTOS<br>NON-OWNED AUTOS ONLY | | | AI2-C21-092036-583<br>AI2-C21-092036-023<br>AI2-C21-092036-943<br>AI5-C21-092036-873 | 1/1/2023<br>1/1/2023<br>1/1/2023<br>1/1/2023 | 1/1/2024<br>1/1/2024<br>1/1/2024<br>1/1/2024 | COMBINED SINGLE LIMIT (Ea accident)<br>BODILY INJURY (Per person)<br>BODILY INJURY (Per accident)<br>PROPERTY DAMAGE (Per accident) | $ 1,000,000<br>$<br>$<br>$ |
| | **UMBRELLA LIAB** OCCUR<br>**EXCESS LIAB** CLAIMS-MADE<br>DED RETENTION $ | | | | | | EACH OCCURRENCE<br>AGGREGATE | $<br>$ |
| B<br>B<br>C | **WORKERS COMPENSATION AND EMPLOYERS' LIABILITY**<br>ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y / N: N<br>If yes, describe under DESCRIPTION OF OPERATIONS below | N / A | | WC5-C25-095741-063<br>WA5-C2D-095741-073<br>WA7-C2D-095741-083 | 1/1/2023<br>1/1/2023<br>1/1/2023 | 1/1/2024<br>1/1/2024<br>1/1/2024 | ✓ PER STATUTE OTH-ER<br>E.L. EACH ACCIDENT<br>E.L. DISEASE - EA EMPLOYEE<br>E.L. DISEASE - POLICY LIMIT | <br>$ 1,000,000<br>$ 1,000,000<br>$ 1,000,000 |

**DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)**

RE: Mira Loma I facility in Nevada.

**CERTIFICATE HOLDER**

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno NV 89521

**CANCELLATION**

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

**AUTHORIZED REPRESENTATIVE**

Joshua Cleveland

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AGENCY CUSTOMER ID: 2-004105

LOC #:

# ADDITIONAL REMARKS SCHEDULE

Page ____ of ____

| AGENCY | NAMED INSURED |
|---|---|
| Liberty Mutual Insurance Co. Nat'l Ins Northeast | UPS SUPPLY CHAIN SOLUTIONS, INC.<br>12380 MORRIS ROAD<br>ALPHARETTA GA 30005 |
| POLICY NUMBER | |
| CARRIER / NAIC CODE | EFFECTIVE DATE: |

## ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability (03/16)

HOLDER: Nevada State Board of Pharmacy

ADDRESS: 985 Damonte Ranch Parkway, Suite 206 Reno NV 89521

If changes/revisions to this certificate are necessary, you may email your request to CMeCertProduction@libertymutual.com.

If you no longer require this certificate and do not need on an annual basis, please email the certificate to our office and instruct us to delete from our database.



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ATTACHMENT

# Establishment Registration & Device Listing



New Search | Back To Search Results

**Establishment:**
UPS Supply Chain Solutions, Inc.
11811 Landon Drive
Suite 100
Mira Loma, CA 91752
**Registration Number:** 3009637528
**FEI Number*:** 3009637528
**Status:** Active
**Date Of Registration Status:** 2023

**Owner/Operator:**
UPS Supply Chain Solutions, Inc.
1920 Outer Loop
Louisville, KY US 40219
**Owner/Operator Number:** 10038314

**Official Correspondent:**
Tim Bishop
1920 Outer Loop
Louisville, KY 40219
**Phone:** 502-6436852

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Page Last Updated: 07/31/2023
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Attachment# 3

# NEVADA STATE BOARD OF PHARMACY

**985 Damonte Ranch Pkwy Suite 206**
**Reno, NV 89521**
**(775) 850-1440**
**Fax: (775) 850-1444**

## PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. E703767

Application/License No. _____

UPS Supply Chain Solutions, Inc., doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
11991 Landon Drive Mira Loma, CA 91751, as
Address of Applicant/Principal
PRINCIPAL, and Great American Insurance Company, a
Surety Company
corporation organized under the laws of the state of Ohio
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
11991 Landon Drive Mira Loma, CA 91751 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 07/19/2021.
Effective Date

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 20th day of July, 2021

APPLICANT/PRINCIPAL

Authorized Representative

SIGNED and SEALED in the presence of:

Witness

Witness

SURETY COMPANY

Lisa Gelsomino

Surety Company's Representative

Lisa Gelsomino, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

# GREAT AMERICAN INSURANCE COMPANY®

Administrative Office: 301 E 4TH STREET • CINCINNATI, OHIO 45202 • 513-369-5000 • FAX 513-723-2740

The number of persons authorized by
this power of attorney is not more than one

Bond No. E703767

## POWER OF ATTORNEY

**KNOW ALL MEN BY THESE PRESENTS:** That the GREAT AMERICAN INSURANCE COMPANY, a corporation organized and existing under and by virtue of the laws of the State of Ohio, does hereby nominate, constitute and appoint the person or persons named below its true and lawful attorney-in-fact, for it and in its name, place and stead to execute on behalf of the said Company, as surety, the specific bond, undertaking or contract of suretyship referenced herein; provided that the liability of the said Company on any such bond, undertaking or contract of suretyship executed under this authority shall not exceed the limit stated below. The bond number on this Power of Attorney must match the bond number on the bond to which it is attached or it is invalid.

| Name | Address | Limit of Power |
|---|---|---|
| Lisa Gelsomino | 150 Northwest Point Blvd.<br>Elk Grove Village, IL 60007 | $25000— |

IN WITNESS WHEREOF the GREAT AMERICAN INSURANCE COMPANY has caused these presents to be signed and attested by its appropriate officers and its corporate seal hereunto affixed this 20th day of July , 2021 .

Attest GREAT AMERICAN INSURANCE COMPANY

Assistant Secretary

*Divisional Senior Vice President*

MARK VICARIO (877-377-2405)

STATE OF OHIO, COUNTY OF HAMILTON - ss:

On this 20th day of July , 2021 , before me personally appeared MARK VICARIO, to me known, being duly sworn, deposes and says that he resides in Cincinnati, Ohio, that he is a Divisional Senior Vice President of the Bond Division of Great American Insurance Company, the Company described in and which executed the above instrument; that he knows the seal of the said Company; that the seal affixed to the said instrument is such corporate seal; that it was so affixed by authority of his office under the By-Laws of said Company, and that he signed his name thereto by like authority.

SUSAN A KOHORST
Notary Public
State of Ohio
My Comm. Expires
May 18, 2025

This Power of Attorney is granted by authority of the following resolutions adopted by the Board of Directors of Great American Insurance Company by unanimous written consent dated June 9, 2008.

*RESOLVED: That the Divisional President, the several Divisional Senior Vice Presidents, Divisional Vice Presidents and Divisonal Assistant Vice Presidents, or any one of them, be and hereby is authorized, from time to time, to appoint one or more Attorneys-in-Fact to execute on behalf of the Company, as surety, any and all bonds, undertakings and contracts of suretyship, or other written obligations in the nature thereof; to prescribe their respective duties and the respective limits of their authority; and to revoke any such appointment at any time.*

*RESOLVED FURTHER: That the Company seal and the signature of any of the aforesaid officers and any Secretary or Assistant Secretary of the Company may be affixed by facsimile to any power of attorney or certificate of either given for the execution of any bond, undertaking, contract of suretyship, or other written obligation in the nature thereof, such signature and seal when so used being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.*

## CERTIFICATION

I, STEPHEN C. BERAHA, Assistant Secretary of Great American Insurance Company, do hereby certify that the foregoing Power of Attorney and the Resolutions of the Board of Directors of June 9, 2008 have not been revoked and are now in full force and effect.

Signed and sealed this 20th day of July , 2021 .

Assistant Secretary

S1194E (05/20)

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

### Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: UPS Supply Chain Solutions, Inc. MDEG License # (if applicable): N/A

Physical Address: 11991 Landon Drive

City: Mira Loma State: CA Zip: 91752

Mailing Address (if different from physical address): **same as physical address**

City: State: Zip:

Telephone: 951-749-3310 Website: www.ups.com

Licensing Company Email: ralicensing@ups.com

### Section 2: Personal Information

First: Marissa Middle: Last: Aispuro

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted] Monte Vista Avenue, SP [redacted]

City: Chino Hills State: CA Zip: 91709

Telephone: [redacted] Email: maispuro@ups.com

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Mount San Antonio College | | 09/10-09/12 | |
| **Address** | **City** | **State** | **Zip** |
| 1100 Grand Ave | Walnut | Ca | 91789 |
| Diploma/Degree obtained, if any | | | |
| N/A | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Don Antonio Lugo High School | | 08/06-06/10 | |
| **Address** | **City** | **State** | **Zip** |
| 13400 Pipeline Ave | Chino | Ca | 91710 |
| Diploma/Degree obtained, if any | | | |
| High School Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

N/A

28-Jul-2023

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 07/94-07/23 | [redacted]Monte Vista Ave spc[redacted] | Chino Hills | Ca | 91709 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

N/A

28-Jul-2023

**Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| UPS Supply Chain Solutions, Inc. | | | 07/22- 07/23 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 11991 Landon Dr | | Mira Loma | Ca | 91752 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| (951) 749-3134 | Operations Supervisor | | 2080 | |
| **Description of Duties** | | | | |
| Involved in daily oversight of receipt, storage, and distribution activities of pharmaceutical products and medical devices; RX and OTC. | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| UPS Supply Chain Solutions, Inc. | | | 07/20-06/22 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 17825 Indian Street | | Moreno Valley | Ca | 92551 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| (951) 749-3134 | Operations Supervisor | | 4160 | |
| **Description of Duties** | | | | |
| Involved in daily oversight of receipt, storage, and distribution activities of pharmaceutical products and medical devices; RX and OTC. | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| UPS Supply Chain Solutions, Inc. | | | 11/13-07/20 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 11811 Landon Drive, Ste 100 | | Mira Loma | Ca | Ca |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| (951) 749-3134 | Operations Supervisor | | 14560 | |
| **Description of Duties** | | | | |
| Involved in daily oversight of receipt, storage, and distribution activities of pharmaceutical products and medical devices; RX and OTC. | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| N/A | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

Continue on next page if additional space is needed.

(10) 28-JUL-2023

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

N/A

(D) 28-Jul-2023

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state? | | ✔ |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline. | | ✔ |

**Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # N/A. **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| | | | | |
| Reason/Charge | | | | |
| N/A | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| | | | | |
| Name of Business/Industry/Entity | | | | |
| | | | | 28-JUL-2023 |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

25 JUL 2023
Date

I, Marissa Aispuro, **certify that as the MDEG Administrator for**

11991 Landon Drive, Mira Loma, CA, 91752,

**that I (initial that you have read and meet the following requirements):**

1. MA Have a high school diploma or its equivalent;
2. MA Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MA Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MA Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Marissa Aispuro
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

25 JUL 2023
Date

| Board Use Only | Date Received: |
|---|---|

Attachment# 1

**UPS Supply Chain Solutions, Inc. ("UPS")**
**11991 Landon Drive**
**Mira Loma, CA 91730**

The MDEG Administrator is a UPS SCS employee who also serves as our Designated Representative for the building.

UPS Supply Chain Solutions, Inc. ("UPS SCS") is a **Third Party Logistics Provider** that provides storage and distribution services to our contracted clients. UPS SCS does not take title or ownership of any pharmaceutical drugs and/or devices nor have responsibility to direct the sale or disposition of these products. Any customer complaints/concerns are forwarded to the contracted client upon receipt for resolution.

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

### Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: UPS Supply Chain Solutions, Inc.

Pharmacy/Wholesaler License # (if applicable): TBD

Physical Address: 11991 Landon Drive

City: Mira Loma State: CA Zip: 91752

Mailing Address (if different from physical address): **same as physical address**

City: State: Zip:

Telephone: 951-749-3310 Website: www.ups.com

Licensing Company Email: ralicensing@ups.com

### Section 2: Personal Information

First: Marissa Middle: Last: Aispuro

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted] Monte Vista Avenue, SP[redacted]

City: Chino Hills State: CA Zip: 91709

Telephone: [redacted] Email: maispuro@ups.com

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Mount San Antonio College | | 09/10-09/12 | |
| Address | City | State | Zip |
| 1100 Grand Ave | Walnut | Ca | 91789 |
| Diploma/Degree obtained, if any | | | |
| N/A | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Don Antonio Lugo High School | | 08/06-06/10 | |
| Address | City | State | Zip |
| 13400 Pipeline Ave | Chino | Ca | 91710 |
| Diploma/Degree obtained, if any | | | |
| High School Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Address | City | State | Zip |
| Diploma/Degree obtained, if any | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Address | City | State | Zip |
| Diploma/Degree obtained, if any | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| Address | City | State | Zip |
| Diploma/Degree obtained, if any | | | |

N/A

28-Jul-2023

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 07/94-07/23 | [redacted] Monte Vista Ave spc [redacted] | Chino Hills | Ca | 91709 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

N/A

28-Jul-2023

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| UPS Supply Chain Solutions, Inc. | | | 07/22- 07/23 |
| **Business Address** | **City** | **State** | **Zip** |
| 11991 Landon Dr | Mira Loma | Ca | 91752 |
| **Phone** | **Title** | | **Number of Employed Hours** |
| (951) 749-3134 | Operations Supervisor | | 2080 |
| **Description of Duties** | | | |
| Involved in daily oversight of receipt, storage, and distribution activities of pharmaceutical products and medical devices; RX and OTC. | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| UPS Supply Chain Solutions, Inc. | | | 07/20-06/22 |
| **Business Address** | **City** | **State** | **Zip** |
| 17825 Indian Street | Moreno Valley | Ca | 92551 |
| **Phone** | **Title** | | **Number of Employed Hours** |
| (951) 749-3134 | Operations Supervisor | | 4160 |
| **Description of Duties** | | | |
| Involved in daily oversight of receipt, storage, and distribution activities of pharmaceutical products and medical devices; RX and OTC. | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| UPS Supply Chain Solutions, Inc. | | | 11/13-07/20 |
| **Business Address** | **City** | **State** | **Zip** |
| 11811 Landon Drive, Ste 100 | Mira Loma | Ca | 91752 |
| **Phone** | **Title** | | **Number of Employed Hours** |
| (951) 749-3134 | Operations Supervisor | | 14560 |
| **Description of Duties** | | | |
| Involved in daily oversight of receipt, storage, and distribution activities of pharmaceutical products and medical devices; RX and OTC. | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | **Number of Employed Hours** |
| | | | |
| **Description of Duties** | | | |
| | | | |

N/A

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | **Number of Employed Hours** |
| | | | |
| **Description of Duties** | | | |
| | | | |

Continue on next page if additional space is needed.

28-JUL-2023

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

N/A

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question #** N/A **. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| Reason/Charge | | N/A | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| Name of Business/Industry/Entity | | | | |

25-Jul-2023

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

25 JUL 2023
Date

I, Marissa Aispuro, **certify that as the designated representative for**

UPS Supply Chain Solutions, Inc., 11991 Landon Drive, Mira Loma, CA, 91752,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. MA I am at least 21 years of age;
3. MA I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MA I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MA I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MA I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MA I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Marissa Aispuro

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

25 JUL 2013

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Marissa Aispuro

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

25 JUL 2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of California, ss. County of San Bernardino

I, Marissa Aispuro, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

25 JUL 2023

**Date**

Subscribed and Sworn to before me this _____ day of _____.

**See Attached Notary Form**

**Notary Public Signature**

**(Seal)**

# California Jurat Loose Certificate

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of San Bernardino } ss.

Subscribed and sworn to (or affirmed) before me this 25 day of July, 2023

by Marissa Aispuro a/k/a

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

Kalan
Notary Public Signature

Seal

KAITLYN ALANIS
COMM. #2444611
Notary Public - California
SAN BERNARDINO COUNTY
My Comm. Exp. Apr. 18, 2027

## Optional Information

To help prevent fraud, it is recommended that you provide information about the attached document below.
***This is not required under California State notary public law.***

Document Title: Designated Representative .. # of Pages: 10

## Notes

Designated Representative Application a/k/a

©2014 Golden State Notary, Inc

| POSITION | Last, First Name |
|---|---|
| LEAD | Acosta, Diana |
| LEAD | Caffey, Mitchell |
| Admin II | Manzo, Carmen |
| Admin II | Saint-laurent, Ashley Nadine |
| Warehouse III | Navarrete, Brian Tony |
| Warehouse III | Rodriguez, Brian |
| Warehouse III | Tec, Marcus |
| Warehouse III | Valdez, Teresita |
| Warehouse II | Buenrostro, Eduardo |
| Admin II | Cummings, Micah |
| LEAD | Bilton, Lusher |
| Warehouse III | Flamenco, Jose |
| Admin II | Coon, Fred |
| Warehouse III | Covarrubias, Rodolfo |
| Warehouse III | Dickie, Robert |
| Warehouse III | Estrada, Herminio |
| LEAD | Gutierrez, Nancy |
| Admin II | Hernandez, Nicholas |
| Warehouse III | Kaloian, Kevin |
| Warehouse III | Martinez, Bianca Vanessa |
| Warehouse III | Martinez, Daisy |
| LEAD | Ramirez, Luis |
| Warehouse III | Sanchez, Manuel |
| Warehouse III | Tinajero, Oscar |
| Warehouse III | Willoughby, David |
| Supervisor | Maldonado, Diego |
| Supervisor | Malave, Luis |
| Supervisor | Ortega, Alexandro |
| Supervisor | Aispuro, Marissa |
| Manager | Reyes, Nolys |

Attachment# 2
(NABP application in progress)

## Carlene Colasanti

**From:** inspections@nabp.pharmacy
**Sent:** Thursday, March 23, 2023 2:19 PM
**To:** Carlene Colasanti
**Cc:** Joe Verdusco; Jesse Anguiano
**Subject:** [EXTERNAL] Cleared for NABP Supply Chain Inspection - UPS Supply Chain Solutions, Inc., Mira Loma, CA
**Attachments:** Documents Required at Inspection - Advance Notification (v4).pdf

CAUTION! This email originated outside of the organization. Please do not open attachments or click links from an unknown or suspicious origin.

Dear Carlene,

This notification is to inform you that UPS Supply Chain Solutions, Inc., Mira Loma, CA has been cleared for its Supply Chain Inspection. **The unannounced inspection of your facility may occur any time within the next eight weeks, without notice.** This timeframe is an estimate and is subject to change pending inclement weather, a significant number of blackout dates for your facility, or other unforeseen circumstances. As a reminder of NABP's and your facility's inspection responsibilities reference the previously emailed *Follow Up Requests* communication. Please note, that any changes submitted including additional blackout dates or application changes will be subject to administrative fees and/or travel change fees, if applicable.

Attached you will find a list of items that your facility must have available during the inspection. Because it is unannounced, NABP recommends sharing the location of these documents or files with multiple staff to ensure there is sufficient awareness in the facility of the impending inspection if you, the contact, are unavailable. If these items and documents are not available, **NABP's inability to access them and complete the inspection in its entirety will be reflected in the report provided to the State Boards of Pharmacy.**

Please visit our FAQ page for information on What are the next steps after I have the inspection [nabp.pharmacy]?

Other questions can be directed to inspections@nabp.pharmacy or 847/391-4539.

Cordially,

**Craig Siwik, SSYBC**
Evaluator, Inspection Programs
P: 847/391-4539
D: 847/391-4435

**National Association of Boards of Pharmacy**
1600 Feehanville Dr, Mount Prospect, IL 60056
www.nabp.pharmacy [nabp.pharmacy] | inspections@nabp.pharmacy
[facebook.com] [twitter.com]
[linkedin.com] [youtube.com]

# 4W

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

**Non-Refundable $1,000 Fee**

Rev (05/12/2022)

| **Where is the facility located?** | | ☐ Nevada ☒ Out-of-State |
|---|---|---|
| **Type of Application (check applicable box)** | | **Wholesaler Business Type (check applicable box)** |
| ☒ New Wholesaler<br>☐ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH _____ | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: Verity Pharmaceuticals Inc.

Physical Address: 850 Bear Tavern Road, Suite 108

City: Ewing State: NJ Zip: 08628

Mailing Address (if different from physical address): 850 Bear Tavern Road, Suite 108

City: Ewing State: NJ Zip: 08628

Telephone: (215) 550-6077 Website: https://veritypharma.com/us

Name of Designated Representative (DR): Wayne Caldwell

Licensing Company Email: statelicensing@veritypharma.com DR Email: w.caldwell@veritypharma.com

| **Entities the Wholesaler will Serve (✓ all applicable)** | **Products to be Handled or Wholesaled (✓ all applicable)** | **Type of Wholesaling (✓ all applicable)** |
|---|---|---|
| ☒ Pharmacies | ☒ Dangerous Drugs | ☐ Manufacturer |
| ☒ Practitioners | ☐ Controlled Substances | ☐ Repacker |
| ☒ Hospitals | ☐ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ☒ Wholesalers | ☐ Others: | ☐ Warehouse |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ☒ Others: Military, LTC | | ☒ Others: Virtual Manufacturer |

| **Section 2: History of Company** | **Yes** | **No** |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | x |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | x |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | x |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | x |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | x |

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: No Suppliers

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

**Section 4: Publicly Traded Corporation**

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: DE

Parent Company (if any): Verity Pharmaceuticals Inc.

Corporation/Organization Name: Verity Pharmaceuticals Inc.

Mailing Address: 850 Bear Tavern Road, Suite 108

City: Ewing State: NJ Zip: 08628

Telephone: 416-800-7771 Email: statelicensing@veritypharma.com

Contact Person Name: Jay Silber

**Section 6: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

**Section 7: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | x |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | x | |
| 1. Copy of FDA registration<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** | | ✓ | | |
| • **List of all partners and their percent ownership.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Verity Pharmaceuticals Inc.
Facility Name

Jay Silber
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

DECEMBER 1, 2022
Date

| Board Use Only | Date Received: 5-11-23 | Amount: 1000.00 CC |
|---|---|---|

**Ownership**

Verity Pharmaceuticals Inc. ("Verity") is a privately owned company. Verity is a New Jersey-based, virtual manufacturer of pharmaceuticals. Verity is incorporated in the state of Delaware.

**Company Information**

Verity Pharmaceuticals Inc.
850 Bear Tavern Road, Suite 108
Ewing, NJ 08628
(215) 550-6077
Tax ID: 84-3880711

https://veritypharma.com/us

statelicensing@veritypharma.com

**Corporate Officers**

Jay Silber, Chief Operating Officer
j.silber@veritypharma.com
Business:
2560 Matheson Blvd East Suite 220
Mississauga, Ontario, Canada L4W4Y9

Scott Doherty, Chief Financial Officer
s.doherty@veritypharma.com
Business:
2560 Matheson Blvd East Suite 220
Mississauga, Ontario, Canada L4W4Y9

| NDC/NHR IC Labeler Code | Firm Name |
|---|---|
| 74676 | Verity Pharmaceuticals Inc. |

5.11.23
BB

# Description of Operations

Verity Pharmaceuticals Inc. is a VirtualManufacturer focusing on clinically relevant, in-demand prescription therapeutics for the benefit of healthcare providers and their patients across a range of therapeutic areas including Urology, Oncology, Infectious Disease and Men's and Women's Health. Verity Pharmaceuticals Inc.'s products are manufactured by a Contract Manufacturer and is distributed to Wholesalers by their Third-Party Logistics Provider, Integrated Commercialization Solutions (ICS), who is licensed to ship pharmaceutical products into your state.

**Product:**
Trelstar
**Labeler Code:**
74676

**CMO Partner(s):**
Debiopharm Research & Manufacturing SA
Case Postale 368 Rue du Levant 146
1920 Martigny, Switzerland
FEIN: 3002806850

Sharp Packaging Solutions
7451 Keebler Way
Allentown PA 18106
FEIN: 3004161147

**THIRD-PARTY LOGISTICS**
Integrated Commercialization Solutions (ICS)
420 International Blvd
Brook, KY 10409

**Description of Facility**
Verity Pharmaceuticals, Inc. does not handle, store or ship commercial product from its facility in Ewing, NJ. This facility is used exclusively for office space.

Verity Pharmaceuticals Inc.'s hours of operation are 9:00 am – 5:00pm Monday through Friday.

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

# National Drug Code Directory

Current through January 03, 2023

**You have searched Finished drug products**

**Search Results:** *'verity'*

Back to Search Page () | Search Again ()

CSV Excel

**Display** 50 **records per page** **Search for text in the table:**

| Proprietary Name | NDC Package Code | Strength | Dosage Form | Route | Appl. No. | Labeler Name | Product NDC | Nonproprietary Name | Substance Name | Product Type Name | Start Marketing Date | End Marketing Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + Trelstar | 74676-5902-1 | | KIT | | NDA020715 | Verity Pharmaceuticals Inc. | 74676-5902 | triptorelin pamoate | | HUMAN PRESCRIPTION DRUG | 06/15/2000 | N/A |
| + Trelstar | 74676-5904-1 | | KIT | | NDA021288 | Verity Pharmaceuticals Inc. | 74676-5904 | triptorelin pamoate | | HUMAN PRESCRIPTION DRUG | 06/29/2001 | N/A |
| + Trelstar | 74676-5906-1 | | KIT | | NDA022437 | Verity Pharmaceuticals Inc. | 74676-5906 | triptorelin pamoate | | HUMAN PRESCRIPTION DRUG | 03/11/2010 | N/A |

Showing 1 to 3 of 3 entries Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)

See also: Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Top (https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm)

# Delaware

The First State



*I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "VERITY PHARMACEUTICALS INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTEENTH DAY OF JANUARY, A.D. 2023.*

*AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.*

*AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "VERITY PHARMACEUTICALS INC." WAS INCORPORATED ON THE EIGHTEENTH DAY OF SEPTEMBER, A.D. 2019.*

*AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.*

Jeffrey W. Bullock, Secretary of State

7613652 8300

SR# 20230171153

Authentication: 202517929

Date: 01-18-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

# NEW JERSEY DEPARTMENT OF HEALTH
## CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0748646

P.O. Box 369, Trenton, New Jersey 08625-0369

## DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: [X] manufacturer [X] wholesaler which conducts business at the following locations in this State:

850 BEAR TAVERN RD, STE 108 EWING, NJ 08628-

Reg. No.
5005971

VERITY PHARMACEUTICALS INC.
850 BEAR TAVERN RD, STE 108
EWING, NJ 08628-

**ISSUED PURSUANT TO**
**N.J.S.A. 24:6B**

**EXPIRES: January 31, 2024**

*Establishment Copy*

New Jersey Department of Health
P.O. Box 369, Trenton, New Jersey 08625-0369
Drug and Medical Device Certificate of Registration

Information recorded in the system as of 1/3/2023

**Registration Number:** 5005971 **Registered as:** Wholesale

**Name:** VERITY PHARMACEUTICALS INC.

**DBA:**

**Address:** 850 BEAR TAVERN RD, STE 108, EWING, NJ 08628

**Original Issue Date:** 07/19/2021 **Expiration Date:** 01/31/2024

**Current Issue Date:** 12/20/2022

**Disciplines:** No

# NEVADA STATE BOARD OF PHARMACY

**985 Damonte Ranch Pkwy Suite 206**
**Reno, NV 89521**
**(775) 850-1440**
**Fax: (775) 850-1444**

## PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 902006997-800153394

Application/License No. _____

VERITY PHARMACEUTICALS, INC. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 850 BEAR TAVERN RD., SUITE 108, EWING, NJ 08628 (Address of Applicant/Principal), as PRINCIPAL, and ATLANTIC SPECIALTY INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of NEW YORK (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 605 HIGHWAY 169N, SUITE 800, PLYMOUTH, MN 55441 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on MARCH 8, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.

(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.

(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.

(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.

(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.

(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.

(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 8TH day of MARCH, 2023.

APPLICANT/PRINCIPAL

Authorized Representative

SIGNED and SEALED in the presence of:

Witness

Witness

SURETY COMPANY

Surety Company's Representative

Julie Turland, Attorney-in-fact

print name

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A

Nevada Resident Agent

intact INSURANCE

# Power of Attorney

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: **James Scharf, Katherine Gill, Ryan Brady, Jim Lazenkas, Richard Longland, Olga Iankine, Dina Amaro-Elias, Kiru Ratnasingam, Justin Eccleston, Kim Roberts, Nelson de Quintal, Korey Pettit, Preya Prashad, Maria Suarez, Fadi Mortada, Bryan Kechnie, James Harris, Cheryl Best-Pope, Jennifer Love, Marisa Medeiros, Anita Rooke, Meaghan Fowler, Mario Vieira, Manni Batwa, Chelsea James, Fernanda de Melo, Karamjit Kaur, Allen Babista, Jenny Wang, Julie Turland, Michele Carpio,** each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this twenty-seventh day of April, 2020.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Paul J. Brehm, Senior Vice President

STATE OF MINNESOTA
HENNEPIN COUNTY

On this twenty-seventh day of April, 2020, before me personally came Paul J. Brehm, Senior Vice President of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and he acknowledged the execution of the same, and being by me duly sworn, that he is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON DWAN NASH-TROUT
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2025

_____
Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 8th day of March, 2023

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

_____
Kara Barrow, Secretary

This Power of Attorney expires
January 31, 2025

Please direct bond verifications to surety@intactinsurance.com

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (04/22/2021)

### Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Verity Pharmaceuticals Inc.

Physical Address 850 Bear Tavern Road, Suite 108

City Ewing State NJ Zip 08628

Mailing Address (if different from physical address) 850 Bear Tavern Road, Suite 108

City Ewing State NJ Zip 08628

Telephone (215) 550-6077 Website https://veritypharma.com/us

Licensing Company Email statelicensing@veritypharma.com

### Section 2: Personal Information

First Wayne Middle David Last Caldwell

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 850 Bear Tavern Road, Suite 108

City Ewing State NJ Zip 08628

Telephone (215) 550-6077 Email w.caldwell@veritypharma.com

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | x |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | x |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | x |

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/Reserves ☐ Navy/Reserves ☐ Airforce/Reserves ☐ Marine Corps/Reserves ☐ Coast Guard/Reserves ☐ National Guard

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | x |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | N/A | |



Applicant's initials TEC

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| University of New Brunswick | | 09/77 - 04/81 | |
| **Address** | **City** | **State** | **Zip** |
| New Brunswick PO Box 4400 E3B 5A3 BEd | Fredericton | Canada | |
| **Diploma/Degree obtained, if any** | | | |
| Science | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| John Rennie High School | | 09/73 - 05/77 | |
| **Address** | **City** | **State** | **Zip** |
| 501 Boul. Saint-Jean Pointe Claire | Quebec | Canada | |
| **Diploma/Degree obtained, if any** | | | |
| HS Diploma | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| **Address** | **City** | **State** | **Zip** |
| **Diploma/Degree obtained, if any** | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| **Address** | **City** | **State** | **Zip** |
| **Diploma/Degree obtained, if any** | | | |
| **School Name** | | **From - To (MM/YY – MM/YY** | |
| **Address** | **City** | **State** | **Zip** |
| **Diploma/Degree obtained, if any** | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 4/18-Current | [redacted] Mahogany Walk | Newtown 15 Min. Drive | PA | 18940 |
| 11/17-4/18 | [redacted] Avalon Ct. | Doylestown | PA | 18901 |
| 10/2000-10/17 | [redacted] Devon Road | Newton | PA | 18940 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Verity Pharmaceuticals | | | 2020 - Present |
| **Business Address** | **City** | **State** | **Zip** |
| 850 Bear Tavern Road, Suite 108 | Ewing | NJ | 08628 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| (215) 550-6077 | Head US Commercial Operations and Marketing | Full time | |

Description of Duties

Established and oversee Verity Pharmaceuticals day-to-day US Operations including working closely with key personal and management to provide strategic leadership, implementation of business plans, ensuring legal and regulatory process adherence, and compliance with laws and regulations

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Diaceutics Inc. | | | 2018 - 2020 |
| **Business Address** | **City** | **State** | **Zip** |
| 2001 Route 46 Waterview Plaza | Parsippany | NJ | 07054 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| N/A | Unit Director | Full Time | |

Description of Duties

Responsible for aligning the organization on the commercial applications of company's data assets.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Prognos | | | 2015 - 2018 |
| **Business Address** | **City** | **State** | **Zip** |
| 85 Broad St, | New York | New York | 10004 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| (888) 506-2660 | Vice President | Full time | |

Description of Duties

Lead for opportunity identification, plan development through execution and delivery.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |

Description of Duties

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |

Description of Duties

Continue on next page if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | x |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | x |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | x |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | x |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | x |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | x |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | x |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | x |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | x |

**I,** Wayne Caldwell **, certify that as the designated representative for**

Verity Pharmaceuticals Inc.,

**that I am qualified as follows and will comply with the following:**

1. I am at least 21 years of age;
3. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. I will serve in this representative capacity for only one pharmacy or wholesaler at a time

Wayne Caldwell

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-16-2022

Date

Applicant's initials

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Wayne Caldwell
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-16-2022
Date

---

**Please have this section completed in the presence of a Notary Public.**

State of PA, ss. County of BUCKS

I, Wayne D Caldwell, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

11-16-2022
**Date**

Subscribed and Sworn to before me this 16 day of NOV 2022.

**Notary Public Signature**

Commonwealth of Pennsylvania - Notary Seal
MICHAEL BERK, Notary Public
BUCKS County
My Commission Expires October 13, 2026
Commission Number 1258131
(Seal)

Applicant's initials

Commonwealth of Pennsylvania - Notary Seal
MICHAEL BERK, Notary Public
BUCKS County
My Commission Expires October 13, 2026
Commission Number 1258131

# Wayne D. Caldwell

[redacted]Mahogany Walk, Newtown, PA 18940

[redacted]


Life Science Professional with deep industry management experience. Comprehensive knowledge of the pharmaceutical space with extensive background in strategy, commercialization, and operational excellence. Strong written and verbal communication skills, proven leader, detail oriented.

## EXPERIENCE

**Verity Pharmaceuticals** Ewing, NJ *2020 - Present*
**Head US Commercial Operations and Marketing**
- Established and oversee Verity Pharmaceuticals day-to-day US Operations including working closely with key personal and management to provide strategic leadership, implementation of business plans, ensuring legal and regulatory process adherence, and compliance with laws and regulations.
- Manage Marketing Team for the development and strategic execution of brand and corporate communications. Track compliance to government regulations, and ensure staff awareness to updates, and overall compliance to processes.

**Diaceutics Inc.** Parsippany, NJ and Dublin, Ireland *2018 - 2020*
**Unit Director**
- Responsible for aligning the organization on the commercial applications of company's data assets. Oversee the planning, development, and execution of the Marketing Strategy by coordinating multiple support teams around shared objectives.
- Role required experience in driving timely and efficient implementation against key performance indicators in a highly regulated, detail-oriented environment.

**Prognos** New York, NY *2015 - 2018*
**Vice President**
- Lead for opportunity identification, plan development through execution and delivery. Primary owner of client negotiations, contracting, and deliverables.
- Role required business process expertise, coordination across multiple stakeholders, and superior time-management skills.

VERITY EMPLOYEE LIST

| First Name | Last Name | Title/Role |
|---|---|---|
| Bill | Schwarzer | NAD |
| Brandi | Cole | RAM |
| Brian | Robb | RAM |
| Cecile | Knight | RAM |
| Christy | Barlow | RAM |
| Dana | Harty | RAM |
| Darren | Johnson | RAM |
| David | Lahey | Data Analytics Manager |
| Denise | Gates | RAM |
| Dylan | Tanner | RAM |
| Frances | Aparicio-Bell | RAM |
| Jalees | Farhan | Senior Manager, Scientific Affairs |
| Jay | Silber | Chief Operations Officer & General Counsel |
| Jennifer (Jenna) | Luciano | RAM |
| Joe | Elliott | Strategic KOL Communications Lead |
| Joel | Moerer | NAD |
| Jose | Santana | Regional Account Director |
| Josefina | Diaz | Sales Representative |
| Katie | Safar | RAM |
| Lisa | Bodker | RAM |
| Luis | Echevarria | Regional Account Manager, Institutional & Trade Relations |
| Marla | Ranft | Nurse Liaison |
| Megan | Black | RAM |
| Mick | White | Manager, Operations |
| Mitchell | Rice | RAM |
| Neil | Fleshner | Chief Medical Officer & CEO |
| Ostap | Mojsiak | |
| Patrick | Mullaney | Marketing Manager |
| Robert | Murphy | VP |
| Samantha | Belmonte | IFS/Sales Rep |
| Scott | Doherty | Chief Financial Officer |
| Shareef | Mohamed | RAM |
| Stephanie | Gonzalez | RAM |
| Wayne | Caldwell | US Commercial |

# 4X

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

| Where is the facility located? | | ☐ Nevada ☒ Out-of-State |
|---|---|---|
| **Type of Application (check applicable box)** | | **Wholesaler Business Type (check applicable box)** |
| ☒ New Wholesaler<br>☐ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH _____ | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: AmerisourceBergen Drug Corporation

Physical Address: 501 W. 44th Ave.

City: Denver State: CO Zip: 80216

Mailing Address (if different from physical address): Legal Dept. – Licensing, 1 West First Avenue

City: Conshohocken State: PA Zip: 19428

Telephone: 720-855-4600 Website: www.amerisourcebergen.com

Name of Designated Representative (DR): Zackrie Reinhart

Licensing Company Email: ABDCDrugLicensing@amerisourcebergen.com DR Email: Zreinhart@amerisourcebergen.com

| Entities the Wholesaler will Serve (✓ all applicable) | Products to be Handled or Wholesaled (✓ all applicable) | Type of Wholesaling (✓ all applicable) |
|---|---|---|
| ☒ Pharmacies | ☒ Dangerous Drugs | ☐ Manufacturer |
| ☒ Practitioners | ☒ Controlled Substances | ☐ Repacker |
| ☒ Hospitals | ☒ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ☒ Wholesalers | ☐ Others: | ☒ Warehouse |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ☐ Others: | | ☐ Others: |

| Section 2: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | x |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | x |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | x | |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | x |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | x |

# AMERISOURCEBERGEN CORPORATION

## COMPLIANCE HISTORY

AmerisourceBergen Corporation ("AmerisourceBergen"), has had the following compliance issues relating to the licensure of its subsidiaries to engage in pharmaceutical distribution:

In September 2017, AmerisourceBergen Specialty Group, LLC ("ABSG"), pled guilty in the Eastern District of New York to a strict liability misdemeanor offense in connection with the failure of one of ABSG's formerly operating entities, Medical Initiatives, Inc., to register with the United States Food and Drug Administration. ABSG paid a fine and forfeiture and entered into a three-year compliance agreement as a result of the plea.

In January 2018, the Colorado Board of Pharmacy cited ABDC's Denver division for a documented loss associated with a controlled substance. As a result of the citation, ABDC paid a small fine.

In April 2018, ABDC's Sacramento division entered into a settlement agreement and disciplinary order for public reproval with the State of California based on allegations that a pharmacist did not sign for certain deliveries of drugs made to a particular pharmacy. As a result of the settlement agreement, ABDC paid a small fine.

In June 2018, the Florida Department of Business and Professional Regulation issued a Notice of Violation, alleging that ASD violated Section 499.067 of the Florida Statutes because ASD's owner, ABSG, was found to have violated a federal drug law. In June 2018, ASD and the Department entered into a Settlement Agreement resolving the matter and paid a fine, without ASD admitting the allegations in the Notice of Violation.

In June 2018, the Board of Pharmacy Department of Consumer Affairs in the state of California issued a Citation to H.D. Smith, LLC (which was acquired by AmerisourceBergen in alleging the violation of California Business and Professional Code 4059.5(a), stating dangerous drugs were signed for by a non-pharmacist in August 2015. In June of 2018, with no admission of guilt, H.D. Smith, LLC resolved the matter and paid a small fine.

In June 2018, the California Board of Pharmacy cited ABDC's Amityville, NY division for allegedly failing to ensure that dangerous drugs are delivered only to authorized premises and received and signed for by a licensed pharmacist. The California Board of Pharmacy issued a citation and, with no admission of guilt, a small fine was paid by ABDC.

In February 2019, the Colorado State Board of Pharmacy cited ABDC's Bethlehem, PA division for failing to timely report a change in Designated Representative and pay the requisite fee. The Colorado State Board of Pharmacy issued a citation and ABDC paid a small fine.

In October 2019 the State of Utah Department of Commerce, Division of Occupational and Professional Licensing (the "Division") issued an administrative citation to the ASD facility located in Dothan, AL for failing to report compliance-related issues to the Division within the 10-day time frame as outlined in U.C. A. 58-17b-614. The facility paid a small fine.

On September 27, 2019 the State of Utah Department of Commerce, Division of Occupational and Professional Licensing (the "Division") issued administrative citations to the ABDC Bethlehem facility and the ABDC Sacramento facility for failing to report compliance-related issues to the Division within the 10-day time frame as outlined in U.C. A. 58-17b-614. Each facility paid a small fine.

In October 2019, the California Board of Pharmacy issued an administrative action against the ABDC Phoenix, Arizona facility for not notifying the Board of Pharmacy of a new Designated Representative-in-Charge within 30-days of the date that the prior Designated Representative ceased to be the Designated Representative-in-Charge. The California Board of Pharmacy issued a Citation and, in resolution of the matter, ABDC paid a small fine.

In January 2020, ABDC's Valencia and Corona Distribution Centers, as well as designated representatives Ronald Green, William Wilson, and John Stavich, entered into a Stipulated Settlement and Disciplinary Order for Public Reproval with the California Board of Pharmacy related to ABDC's sale of certain controlled substances to four pharmacies during various times between 2010 and 2015. The ABDC entities paid a fine and its licenses were subject to public reproval as a result of the settlement.

In January 2020, the Alabama Board of Pharmacy issued a Statement of Charges and Notice of Hearing alleging ASD Specialty Healthcare, LLC dba Oncology Supply's facility in Dothan, AL violated the Alabama Pharmacy Practice Act because of a Plea Agreement entered into by ASD's owner, AmerisourceBergen Specialty Group, in the E.D. N.Y. in September of 2017 and a Settlement Agreement ASD entered into with the State of Florida in July of 2018. In July 2020, ASD and the Department entered into a Consent Order resolving the matter and paid a fine.

In June 2020, an administrative citation was issued to ABDC's Olive Branch division by the State of California, based on allegations that a pharmacist did not sign for certain deliveries of drugs made to a pharmacy. As a result, ABDC paid a small fine.

In June 2020, the State of the Maine Board of Pharmacy issued an administrative citation to the ASD facility located in Dothan, AL for failing to report its 2018 settlement with the Florida Dept. of Professional and Business Regulation to the Maine Board within the 10-day time frame as outlined in 10 M.R.S. §§ 8003(5-A)(A)(1 l); and 10 M.R.S. § 8003-G(2)(C). In July 2020 the facility entered into a settlement agreement with the Board and paid a small fine.

In July 2020, ABDC's Sacramento Distribution Center, as well as designated representative John E. Jessee, entered into a Stipulated Settlement and Disciplinary Order with the California Board of Pharmacy related to ABDC's sale of certain controlled substances to four pharmacies during various times between 2010 and 2014. With no admission of guilt, ABDC paid a fine and its wholesale license and designated representative, John E. Jessee's license, were subject to public reproval as a result of the settlement.

In September 2020, administrative citations were issued to ABDC's Sacramento division and the Designated Representative Richard Wilson by the State of California, based on allegations that a pharmacist did not sign for certain deliveries of drugs made to a pharmacy. The Sacramento facility contested the citations and has requested an office hearing with CA BOP to discuss.

In November 2020, ABDC entered into a settlement agreement with the Florida Department of Business and Professional Regulation to resolve allegations that ABDC's Louisville, Kentucky division operated without a permit, adulterated prescription drugs by distributing drugs without a permit, and failed to maintain records as required by Florida law. As a result of the settlement, ABDC paid a fine but did not admit guilt.

In January 2021, ICS entered into a settlement agreement with the Florida Department of Business and Professional Regulation to resolve allegations that ICS's Lockbourne, Ohio distribution center division operated as Florida-licensed out of state prescription drug wholesale distributor without a licensed Florida Certified Designated Representative in its employ, as required by Florida law. As a result of the settlement, ICS paid a fine but did not admit guilt.

In February 2021, ABDC entered into a settlement agreement with The State of Connecticut, Dept. of Consumer Protection to resolve allegations that ABDC Newburgh, through its contracted carrier, failed to maintain all equipment used for storage of controlled substances securely locked except for the actual time required to remove or replace needed items. As a result of the settlement, ABDC paid a fine.

In February 2021, the Alabama Board of Pharmacy issued a Statement of Charges and Notice of Hearing alleging ABDC's facility in Louisville, KY violated the Alabama Pharmacy Practice Act because of a settlement agreement entered into in November 2020 with the Florida Department of Business and Professional Regulation to resolve allegations that ABDC's Louisville, Kentucky division operated without a permit, adulterated prescription drugs by distributing drugs without a permit, and failed to maintain records as required by Florida law. In August 2021, ABDC and the Board entered into a Consent Order resolving the matter and paid a fine.

In May 2021, the Maine Board of Pharmacy and ABDC's Bethlehem, PA division entered into a consent agreement with respect to ABDC failing to report compliance-related issues to the Board within the 10-day time frame as outlined in 10 M.R.S. § 8003-G(2)(C). As a result, ABDC paid a small fine.

In June 2021, ABDC and the Michigan Department of Licensing and Regulatory Affairs entered into a consent order resolving the ABDC Olive Branch, MS alleged violation of MCL 333.17768(2)(d) due to Officers maintaining a financial interest in ABDC, whose license was subject to an administrative penalty in California in December 2020. ABDC agreed to pay a small fine, which was fully processed in November 2021, fully closing out the matter.

In November 2021, administrative citations were issued to the wholesale license of ABDC's Sacramento division, and the license of its Designated Representative, Richard Wilson, by the State of California, based on allegations that a pharmacist did not sign for certain deliveries of drugs made to a pharmacy. As a result, ABDC provided proof of abatement as requested by the State and paid a reduced fine amount in January 2022 to close out the citations.

In May 2022, the Colorado Board of Pharmacy issued a Letter of Admonition to ABDC's Sugar Land, TX division for violation of Board Rule 15.01.14(c), for ABDC's failure to notify the Board within 30 days of the change of the designated representative of ABDC Sugar Land's Colorado wholesale distributor license. The Board took no further action other than the issuance of the letter, thus closing out the matter.

In June 2022, the California Board of Pharmacy issued a citation against the ABDC Morrisville, NC facility for not notifying the Board of Pharmacy of a new Designated Representative-in-Charge within 30-days of the date that the prior Designated Representative ceased to be the Designated Representative-in-Charge. In September 2022, ABDC paid a small fine to resolve the citation.

In November 2022, ABDC's Columbus, OH division entered into a settlement agreement with the Ohio Board of Pharmacy to resolve the complaint brought by the Board that alleged violations of sections of OH Rule 4729, for an alleged failure to verify OH licensure of the selling entity before any purchase or sale of a "dangerous drug", as defined by OH law. As a result of the settlement, ABDC paid a fine but did not admit guilt.

In November 2022, ABDC and the Massachusetts Board of Registration in Pharmacy entered into a consent agreement resolving the complaint against its Massachusetts license alleging that disciplinary action was warranted under M.G.L. c. 112, §§ 42A & 61 and 247 CMR 10.03(1)(v), due to an unresolved loss of 100 amphetamine salt 10 mg tablets. With no admission of guilt, ABDC entered into a consent agreement for reprimand with the Massachusetts Board of Registration in Pharmacy.

In December 2022, ASD Specialty Healthcare, LLC dba Oncology Supply ("Oncology Supply") entered into a stipulated order resolving Case No. 20 PHM 123, brought against it by the Wisconsin Pharmacy Examining Board. The case alleged that Oncology Supply's facility located in Dothan, AL violated Wisconsin pharmacy law because of a plea agreement ASD's owner, AmerisourceBergen Specialty Group, entered into in the E.D. N.Y. in September of 2017 for violations of federal drug laws, a Settlement Agreement ASD entered into with the State of Florida in July of 2018 for an alleged violation of Florida law for the 2017 ABSG plea agreement, the 2020 consent agreement ASD entered into with the Maine Board of Pharmacy alleging violation of Maine pharmacy law because of the previous 2017 ABSG plea and the subsequent 2018 Florida settlement, and finally the 2020 consent order entered into with the Alabama Board of Pharmacy for the alleged violations of Alabama law because of the 2017 plea agreement, 2018 Florida settlement, and 2020 Maine consent order. As a result of the Wisconsin order, Oncology Supply was issued a reprimand and required to pay a forfeiture and costs to resolve the matter.

In February 2023, the California Board of Pharmacy issued a citation against the ABDC Honolulu, HI facility for not notifying the Board of Pharmacy of a new Designated Representative-in-Charge within 30-days of the date that the prior Designated Representative ceased to be the Designated Representative-in-Charge. ABDC paid a small fine to resolve the citation and the matter was closed out in April 2023.

COLORADO
Department of
Regulatory Agencies
Division of Professions and Occupations

March 20, 2018

AmerisourceBergen Drug Corporation
Attn: Randy Lewis
Director, Corporate Security and Regulatory Affairs
P. O. Box 959
Valley Forge, PA 19482
1300 Morris Drive
Chesterbrook, PA 19087-5594

Sent via email: rlewis@amerisourcebergen.com

RE: Case 2017-3061 - Stipulation and Final Agency Order

Dear Mr. Lewis:

Staff for the Colorado State Board of Pharmacy ("Board") has reviewed the terms and conditions of the above listed Stipulation and Final Agency Order effective January 24, 2018.

After due consideration, and pursuant to Board Policy 10-6, staff for the Board released you from the terms and conditions of the January 24, 2018 Stipulation and Final Agency Order and restored your Registration WHI 6014 to unencumbered status, effective March 14, 2018.

Your cooperation during the pendency of this matter is sincerely appreciated.

Respectfully,

FOR THE COLORADO STATE BOARD OF PHARMACY

Wendy Anderson
Program Director

cc: Christopher Casalenuovo, Esq., sent via email: ccasalenuovo@amerisourcebergen.com

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2017-3061

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**STIPULATION AND FINAL AGENCY ORDER**

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IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE NON-RESIDENT WHOLESALER REGISTRATION IN THE STATE OF COLORADO OF AMERISOURCEBERGEN DRUG CORPORATION, REGISTRATION NO. WHI 6014,

Respondent Outlet.

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IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and AmerisourceBergen Drug Corporation ("Respondent Outlet") to resolve all matters pertaining to Board Case Number 2017-3061, as follows:

## FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Outlet, its registration as an in-state wholesaler, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act at Title 12, Article 42.5, C.R.S. (2017).

2. Respondent Outlet was originally registered in the State of Colorado on or about December 7, 2006, being issued registration number WHI 6014, and has been so registered at all times relevant to this disciplinary action.

3. Respondent Outlet's address of record with the Board and current location is 501 W. 44th Ave., Denver, CO 80216.

4. Respondent Outlet admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

5. On or around March 10, 2017, Respondent Outlet could not account for 720 tablets of a schedule II controlled substance.

6. Respondent Outlet's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

## Colorado Revised Statutes

**12-42.5-123. Unprofessional conduct - grounds for discipline.**

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(I) Any of the provisions of this article, including commission of an act declared unlawful in section 12-42.5-126;

(II) The lawful rules of the board;

(k) Has failed to meet generally accepted standards of pharmacy practice.

## Pharmacy Board Rules and Regulations

**15.05.10.d.** All facilities shall be equipped with inventory management and control systems that detect, protect against, and document any instances of theft, diversion, or counterfeiting.

## TERMS OF DISCIPLINE

7. Fine with Surcharge. Pursuant to §12-42.5-124(5)(a)(I), C.R.S., Respondent Outlet shall pay a fine of Two Thousand Five Hundred Dollars and No Cents ($2,500.00). Respondent Outlet understands and acknowledges that, pursuant to §24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall impose an additional surcharge of 15% of this fine. Respondent Outlet shall therefore pay a total amount of Two Thousand Eight Hundred Seventy Five Dollars and No Cents **($2,875.00)**. The total amount shall be payable to the State of Colorado and shall be remitted in one (1) lump sum to be included when Respondent Outlet submits this signed Final Agency Order to the Board. Respondent Outlet shall write its registration number (WHI 6014) and the case number (2017-3061) on the check.

8. Other Requirements. Respondent Outlet acknowledges and agrees that, as a condition of this Final Agency Order, Respondent Outlet shall:

a. promptly pay all Respondent Outlet's own fees and costs associated with this Final Agency Order;

b. comply fully with this Final Agency Order; and

c. comply fully with the Pharmacists, Pharmacy Businesses and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

9. **Advisements and Waivers.** Through its undersigned Authorized Representative, Respondent Outlet enters into this Final Agency Order freely and voluntarily, after having the opportunity to consult with legal counsel and/or choosing not to do so. Respondent Outlet acknowledges its understanding that it has the following rights:

a. to have formal notice of hearing and charges served upon it;

b. to respond to said formal notice of charges;

c. to have a formal disciplinary hearing pursuant to §§12-42.5-123 and 12-42.5-124, C.R.S.; and

d. to appeal this Final Agency Order.

Respondent Outlet freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent Outlet to the sanctions imposed herein.

10. **Acknowledgments.** The undersigned Authorized Representative of Respondent Outlet has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel and/or choosing not to do so, that Respondent Outlet understands the legal consequences and agrees that none of the terms or conditions herein is unconscionable. Respondent Outlet is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Outlet further acknowledges that it is not entering into this Final Agency Order under any duress.

11. **Violations.** Time is of the essence in this Final Agency Order. It is the responsibility of Respondent Outlet to take all appropriate steps to comply fully with this Final Agency Order. Respondent Outlet acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under §12-42.5-124(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent Outlet's registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Outlet to comply with all terms and conditions of this Final Agency Order.

12. **Completion of Terms.** Upon satisfactory completion of all terms and conditions set forth in this Final Agency Order, the Board shall release Respondent Outlet from the Final Agency Order, and Respondent Outlet's registration will be restored to active and unencumbered status.

13. Integration and Severability. Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

14. Public Record. Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

15. Board Order. This Final Agency Order shall become an order of the Board when it is accepted and signed by the Program Director or authorized Board representative.

16. Effective Date. This Final Agency Order shall become effective upon (a) mailing by first-class mail to Respondent Outlet at Respondent Outlet's address of record with the Board, or (b) service by electronic means on Respondent Outlet at Respondent Outlet's electronic address of record with the Board. Respondent Outlet hereby consents to service by electronic means if Respondent Outlet has an electronic address on file with the Board.

ACCEPTED AND AGREED BY

Respondent Outlet

Trant BAA Director, Operations Dated: 1/22/18
Authorized Representative / Title

Subscribed and sworn to before me in the County of Denver, State of Colorado, this 22 day of January, 2018, by Trant Battarsby, authorized representative of AmerisourceBergen Drug Corporation.

My commission expires: Oct. 19, 2021

Notary Public

KATHLENE J GORDON
Notary Public – State of Colorado
Notary ID 20094033783
My Commission Expires Oct 19, 2021

## FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 24th day of January, 2018.

**State Board of Pharmacy**

BY: Wendy Anderson

Wendy Anderson
Program Director

## CERTIFICATE OF SERVICE

This is to certify that I have duly served the within fully executed **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by electronic means or by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 24 day of JANUARY 2018, addressed as follows:

By electronic mail to Respondent:
AmerisourceBergen Drug Corporation
Attn: Randy Lewis
Director, Corporate Security & Regulatory Affairs
P.O. Box 959
Valley Forge, PA 19482
1300 Morris Drive
Chesterbrook, PA 19087-5594
Email: rlewis@amerisourcebergen.com

By electronic mail to Respondent's counsel:
Christopher Casalenuovo, Esq.
Assistant General Counsel
AmerisourceBergen
Email: ccasalenuovo@amerisourcebergen.com

Agent of the Board

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| | | | | |
| Reason/Charge | | | | |
| | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| | | | | |
| Name of Business/Industry/Entity | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

Date

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: No suppliers sold, dispensed, or distributed w/i last year

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

**Section 4: Publicly Traded Corporation**

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: DE

Parent Company (if any): AmerisourceBergen Services Corporation

Corporation/Organization Name: AmerisourceBergen Drug Corporation

Mailing Address: Legal Dept. – Licensing, 1 West First Avenue

City: Conshohocken State: PA Zip: 19428

Telephone: 610-727-7000 Email: ABDCDrugLicensing@amerisourcebergen

Contact Person Name: Samuel Smith

**Section 6: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

**Section 7: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | x | |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | | x |
| 1. Copy of FDA registration<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** | | ✓ | | |
| • **List of all partners and their percent ownership.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

AmerisourceBergen Drug Corporation

Facility Name

Samuel Smith

Print Name of Authorized Person Submitting Application

Samuel Smith

Original signature of Authorized Person (copies or stamps not accepted)

03/01/23

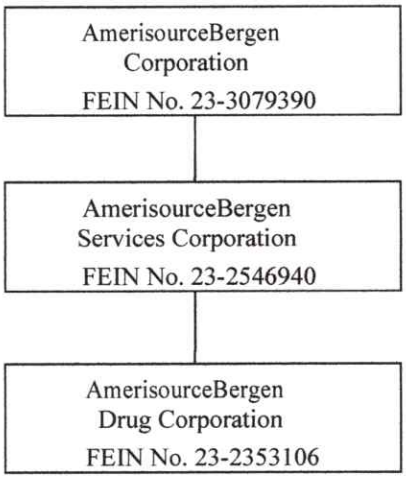
Date

| Board Use Only | Date Received: 6-15-23 | Amount: 1000.00 CC |
|---|---|---|

AmerisourceBergen

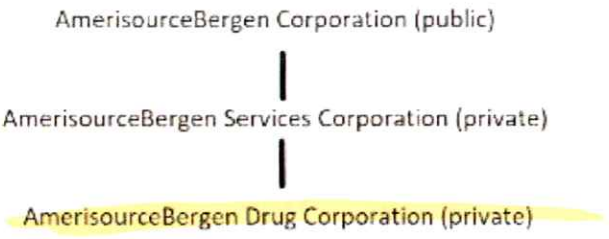
## AMERISOURCEBERGEN DRUG CORPORATION

Organization Flow Chart




| Entity | Parent Company | Percentage Owned |
|---|---|---|
| AmerisourceBergen Drug Corporation | AmerisourceBergen Services Corporation | 100% |
| AmerisourceBergen Services Corporation | AmerisourceBergen Corporation | 100 % Publicly Held |

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AmerisourceBergen Corporation (public)
AmerisourceBergen Services Corporation (private)
AmerisourceBergen Drug Corporation (private)

AmerisourceBergen

**ABDC Denver Facility Security**

AmerisourceBergen Denver facility is equipped with a security system. The security system includes Door Access Control/Alarm for all entrance doors via key card access. All entrance doors into the office and warehouse areas require a key card to access. The security system is monitored 24 hours / 7 days. The system is monitored through Securitas. All alarms are reported by Securitas Central Monitoring station to an AmerisourceBergen designated alarm responder.

**AMERISOURCEBERGEN DRUG CORPORATION**
**501 W. 44th Avenue**
**Denver, CO 80216**

a Delaware corporation
Date of Incorporation – June 24, 1985
FEIN: 23-2353106

## BUSINESS DESCRIPTION

AmerisourceBergen Drug Corporation, a Delaware corporation, is owned 100% by AmerisourceBergen Services Corporation, a Delaware corporation which is owned 100% by AmerisourceBergen Corporation, a Delaware corporation. AmerisourceBergen Corporation is a publicly traded corporation.

AmerisourceBergen Drug Corporation, Denver, CO (the "Facility"), is a wholesale drug distributor of brand name, generic and biotech pharmaceuticals, over-the-counter products and health and beauty care products to retail pharmacies, government institutions, home infusions, specialty pharmacies and managed care markets. The Facility is also licensed to sell controlled substances and holds a DEA license for Schedule II, III, IV and V distribution.

# NABP ACCREDITED
## DRUG DISTRIBUTOR

AmerisourceBergen Drug Corporation

located at

501 W 44th Ave, Denver, CO 80216

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

**Carmen A. Catizone,** MS, RPh, DPh
*Executive Director/Secretary*

12/17/2019 - 12/16/2022
Period of Accreditation

NABP
National Association of Boards of Pharmacy

Main Menu

# Accredited Drug Distributors

**Find an Accredited Drug Distributor**

Facility Name

State (All)

Search Reset

Current list of 1 NABP-Accredited Drug Distributors

Accreditation is valid for 3 years

Facilities listed with "Reaccreditation in process" remain accredited throughout the reaccreditation process.

| Name | Address | Accreditation Date |
|---|---|---|
| AmerisourceBergen Drug Corporation | CO | Reaccreditation in process |

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AmerisourceBergen

# AMERISOURCEBERGEN DRUG CORPORATION

a Delaware corporation
Date of Incorporation – June 24, 1985
FEIN: 23-2353106

## OWNERSHIP

AmerisourceBergen Drug Corporation (FEIN: 23-2353106), a Delaware corporation is owned 100% by AmerisourceBergen Services Corporation (FEIN: 23-2546940), a Delaware corporation, which is owned 100% by AmerisourceBergen Corporation, a Delaware corporation. AmerisourceBergen Corporation (FEIN: 23-3079390) is a publicly traded corporation. The corporate headquarters for each of AmerisourceBergen Drug Corporation, AmerisourceBergen Services Corporation and AmerisourceBergen Corporation is located at 1 West First Ave., Conshohocken, PA 19428.

## DIRECTORS

| NAME | BUSINESS ADDRESS |
|---|---|
| Steven H. Collis | 1 West First Avenue<br>Conshohocken, PA 19428 |
| James F. Cleary, Jr. | 1 West First Avenue<br>Conshohocken, PA 19428 |

## OFFICERS *(partial list)*

| NAME | TITLE | DOB & DL NO. | RESIDENTIAL ADDRESS | BUSINESS ADDRESS |
|---|---|---|---|---|
| Steven H. Collis | Chief Executive Officer | Date of Birth: [redacted]<br>DL No. [redacted] PA)<br>SS#: [redacted] | [redacted] Portledge Drive<br>Bryn Mawr, PA 19010 | 1 West First Avenue<br>Conshohocken, PA 19428 |
| James F. Cleary, Jr. | Executive Vice President, Chief Financial Officer | Date of Birth: [redacted]<br>DL No.: [redacted] PA)<br>SS#: [redacted] | [redacted]S. 18th St., Suite [redacted]<br>Philadelphia, PA 19103 | 1 West First Avenue<br>Conshohocken, PA 19428 |
| Samuel MacLaren Smith | Counsel, Assistant Secretary | Date of Birth: [redacted]<br>DL No.: [redacted] A)<br>SS#: [redacted] | [redacted]W Queen Ln [redacted]<br>Philadelphia, PA 19129 | 1 West First Avenue<br>Conshohocken, PA 19428 |

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# Delaware

The First State



I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "AMERISOURCEBERGEN DRUG CORPORATION" IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SIXTH DAY OF SEPTEMBER, A.D. 2022.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

2064895 8300

SR# 20223617030

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204478687

Date: 09-26-22

COLORADO
Department of Regulatory Agencies
Division of Professions and Occupations

Below are your electronic wallet cards to use as proof of your license. You can also print your license at any time by visiting www.colorado.gov/dora/DPO_Print_License and following the instructions listed.

If you would like a more durable wallet card option, you can order one for a fee by visiting www.nasbastore.org and selecting the "Colorado License Cards" link on the left hand side of the page. If you prefer, you can also contact NASBA by phone at 1-888-925-5237 or by email at nasbastore@nasba.org.

Should you have questions about your credential, or need other information please contact our Customer Service Team at 303-894-7800 or dora_dpo_licensing@state.co.us.

**Colorado Department of Regulatory Agencies**
**Division of Professions and Occupations**

State Board of Pharmacy
AmerisourceBergen Drug Corporation

Wholesaler In-State

WHI.0006014 — **Number**
11/01/2022 — **Issue Date**
Active — **Credential Status**
10/31/2024 — **Expire Date**
Verify this credential at: dpo.colorado.gov

Division Director: Ronne Hines | Credential Holder Signature

**Colorado Department of Regulatory Agencies**
**Division of Professions and Occupations**

State Board of Pharmacy
AmerisourceBergen Drug Corporation

Wholesaler In-State

WHI.0006014 — **Number**
11/01/2022 — **Issue Date**
Active — **Credential Status**
10/31/2024 — **Expire Date**
Verify this credential at: dpo.colorado.gov

Division Director: Ronne Hines | Credential Holder Signature

# Lookup Detail View

### Licensee Information

*This serves as primary source verification* of the license.*

**Primary source verification: License information provided by the Colorado Division of Professions and Occupations, established by 24-34-102 C.R.S.*

| Name | DBA | Public Address |
|---|---|---|
| AmerisourceBergen Drug Corporation | | 501 W 44th Ave<br>Denver, CO 80216 |

### Credential Information

| License Number | License Method | License Type | License Status | Original Issue Date | Effective Date | Expiration Date |
|---|---|---|---|---|---|---|
| WHI.0006014 | Original | Wholesaler In-State | Active | 12/07/2006 | 11/01/2022 | 10/31/2024 |

### Board/Program Actions

| Case Number | Public Action | Resolution | Effective Date | Completed Date |
|---|---|---|---|---|
| 2009-2551 | CLS Stipulation | Stipulation | 06/24/2009 | 06/24/2009 |
| 2017-3061 | CLS Stipulation | Stipulation | 01/24/2018 | 03/14/2018 |

### Online Documents

To view specific documents related to a licensee, use the "External Document" link below. If you would like to search all available online documents use our DPO Public Documents System (http://www.dora.state.co.us/pls/real/DDMS_Search_GUI.DPO_Search_Form). Once there you may enter the licensee name or license number to complete the search. All public documents related to the licensee will be visible upon completion of the search.

If you have any questions or further issues, please contact us at dora_dpo_onlinelicenses@state.co.us.

| Link | Unique ID Number | DocType | DocSource |
|---|---|---|---|
| External Document (http://apps.colorado.gov/dora/licensing/Lookup/LicenseLookup.aspx?docExternal=121533&docGuid=BBEB4E06-FD94-46F2-9889-D3E8020A51C3) | 121533 | BOARD/PROGRAM ACTION DOCUMENTS | IMAGE |

| Link | Unique ID Number | DocType | DocSource |
|---|---|---|---|
| External Document (http://apps.colorado.gov/dora/licensing/Lookup/LicenseLookup.aspx?docExternal=637440&docGuid=6FD68BF7-201C-42A5-B078-1FB344C8D05E) | 637440 | BOARD/PROGRAM ACTION DOCUMENTS | IMAGE |

Generated on: 4/17/2023 1:05:07 PM

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| RA0290988 | 07-31-2023 | $1850 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N,3, 3N,4,5 | DISTRIBUTOR | 06-27-2022 |

AMERISOURCEBERGEN DRUG CORP
501 WEST 44TH AVE
DENVER, CO 80216

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

**THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.**

**CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE**
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| RA0290988 | 07-31-2023 | $1850 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N,3, 3N,4,5 | DISTRIBUTOR | 06-27-2022 |

AMERISOURCEBERGEN DRUG CORP
501 WEST 44TH AVE
DENVER, CO 80216

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| RA0290988 | 07-31-2023 | $1850 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N,3, 3N,4,5 | DISTRIBUTOR | 06-27-2022 |

AMERISOURCEBERGEN DRUG CORP
501 WEST 44TH AVE
DENVER, CO 80216

**CONTROLLED SUBSTANCE/REGULATED CHEMICAL**
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

**THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.**

Form DEA-223/511 (9/2016)

**REPORT**

**CHANGES**

**PROMPTLY**

REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:
   **Drug Enforcement Administration**
   **P.O. Box 2639**
   **Springfield, VA 22152-2639**

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

ACORD®

# CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 04/28/2023

**THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.**

**IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).**

| | |
|---|---|
| **PRODUCER**<br>Marsh USA LLC<br>1717 Arch Street<br>Philadelphia, PA 19103<br>Attn: Jacqueline Mastrangelo 215-246-1399 fax<br><br>CN101440504-MAIN-10M-23-24 | **CONTACT NAME:**<br>**PHONE (A/C, No, Ext):** **FAX (A/C, No):**<br>**E-MAIL ADDRESS:** |
| **INSURED**<br>AmerisourceBergen Corporation ("ABC")<br>& its subsidiary corporations<br>& any formed/acquired entity ABC<br>has majority Interest<br>1 West First Avenue<br>Conshohocken, PA 19428 | **INSURER(S) AFFORDING COVERAGE** — **NAIC #**<br>**INSURER A :** ACE Property And Casualty Ins Co — 20699<br>**INSURER B :** Underwriters at Lloyd's London (IL) — 15792<br>**INSURER C :** Lloyds Syndicate 2623<br>**INSURER D :**<br>**INSURER E :**<br>**INSURER F :** |

**COVERAGES** **CERTIFICATE NUMBER:** CLE-005626193-19 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

| INSR LTR | TYPE OF INSURANCE | ADDL INSD | SUBR WVD | POLICY NUMBER | POLICY EFF (MM/DD/YYYY) | POLICY EXP (MM/DD/YYYY) | LIMITS | |
|---|---|---|---|---|---|---|---|---|
| A | X **COMMERCIAL GENERAL LIABILITY**<br>CLAIMS-MADE [X] OCCUR<br>SEE NOTE #1 BELOW<br>GEN'L AGGREGATE LIMIT APPLIES PER:<br>[X] POLICY [ ] PRO-JECT [ ] LOC<br>OTHER: | | | XEU G27978812 008<br>SEE NOTE #1 BELOW | 05/01/2023 | 05/01/2024 | EACH OCCURRENCE<br>DAMAGE TO RENTED PREMISES (Ea occurrence)<br>MED EXP (Any one person)<br>PERSONAL & ADV INJURY<br>GENERAL AGGREGATE<br>PRODUCTS - COMP/OP AGG<br> | $ 10,000,000<br>$ Excluded<br>$ Excluded<br>$ Included<br>$ 10,000,000<br>$ Excluded<br>$ |
| | **AUTOMOBILE LIABILITY**<br>ANY AUTO<br>OWNED AUTOS ONLY<br>HIRED AUTOS ONLY<br>SCHEDULED AUTOS<br>NON-OWNED AUTOS ONLY | | | NOT PROVIDED BY MARSH USA, INC. | | | COMBINED SINGLE LIMIT (Ea accident)<br>BODILY INJURY (Per person)<br>BODILY INJURY (Per accident)<br>PROPERTY DAMAGE (Per accident)<br> | $<br>$<br>$<br>$<br>$ |
| | **UMBRELLA LIAB** OCCUR<br>**EXCESS LIAB** CLAIMS-MADE<br>DED RETENTION $ | | | | | | EACH OCCURRENCE<br>AGGREGATE<br> | $<br>$<br>$ |
| | **WORKERS COMPENSATION AND EMPLOYERS' LIABILITY** Y/N<br>ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [N] **(Mandatory in NH)**<br>If yes, describe under DESCRIPTION OF OPERATIONS below | N/A | | NOT PROVIDED BY MARSH USA, INC. | | | PER STATUTE / OTH-ER<br>E.L. EACH ACCIDENT<br>E.L. DISEASE - EA EMPLOYEE<br>E.L. DISEASE - POLICY LIMIT | <br>$<br>$<br>$ |
| B | LIFE SCIENCE RISK - PRODUCTS | | | SEE NOTE #2 BELOW | 05/01/2023 | 05/01/2024 | EACH CLAIM/AGGREGATE | 10,000,000 |
| C | TECHNOLOGY E&O LIABILITY | | | W32391220101 | 05/01/2022 | 07/30/2023 | EACH CLAIM/AGGREGATE | 10,000,000 |

**DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)**

Note #1: General liability is written over a Self-Insured Retention of $1 million.

Note #2 – Medical professional liability is underwritten on a claims made basis and subject to a $1 million Self-Insured Retention.

Note #3 – Technology errors and omission ("E&O"), including cyber, privacy and professional liability is written on a claims made basis subject to deductibles at the insured's discretion.

Note #4 – Evidence of insurance for AmerisourceBergen Corporation, Its subsidiaries and divisions.

**CERTIFICATE HOLDER**

Evidence of insurance for
AmerisourceBergen Corporation,
Its subsidiaries and divisions

**CANCELLATION**

**SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.**

**AUTHORIZED REPRESENTATIVE**

Marsh USA Inc.

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The ACORD name and logo are registered marks of ACORD

a Delaware corporation
Date of Incorporation – June 24, 1985
FEIN: 23-2353106

## AMERISOURCEBERGEN DRUG CORPORATION – Employee List

### DIRECTORS

| NAME | BUSINESS ADDRESS |
|---|---|
| Steven H. Collis | 1 West First Avenue<br>Conshohocken, PA 19428 |
| James F. Cleary, Jr. | 1 West First Avenue<br>Conshohocken, PA 19428 |

### OFFICERS *(partial list)*

| NAME | TITLE | BUSINESS ADDRESS |
|---|---|---|
| Steven H. Collis | Chief Executive Officer | 1 West First Avenue<br>Conshohocken, PA 19428 |
| James F. Cleary, Jr. | Executive Vice President, Chief Financial Officer | 1 West First Avenue<br>Conshohocken, PA 19428 |
| Samuel MacLaren Smith | Counsel, Assistant Secretary | 1 West First Avenue<br>Conshohocken, PA 19428 |

| DIRECTOR OF OPERATIONS | BUSINESS ADDRESS | PHONE | E-MAIL |
|---|---|---|---|
| James McMichael | 501 W. 44th Avenue, Denver, CO 80216 | 720-855-4624 | jmcmichael@amerisourcebergen.com |

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# AMERISOURCEBERGEN DRUG CORPORATION

## Denver, CO

| DC | LICENSE TYPE | STATE | LICENSE NO. | EXPIRATION |
|---|---|---|---|---|
| | | | | |
| Denver | Designated Representative | CA | EXC 26624 | 5/1/2023 |
| Denver | Wholesale Drug Distributor | CA | OSD 4609 | 6/1/2023 |
| Denver | Wholesale Drug Distributor | CO | WHI.0006014 | 10/31/2024 |
| Denver | DEA | DEA | RA0290988 | 7/31/2023 |
| Denver | Wholesale Drug Distributor | MI | 5306001415 | 8/7/2024 |
| Denver | Controlled Substances | MI | 5315203520 | 8/7/2024 |
| Denver | Wholesale Drug Distributor | MO | 2002028650 | 10/31/2023 |
| Denver | Wholesale Drug Distributor | MS | 16712/16.5a | 12/31/2023 |
| Denver | Controlled Substance | MS | CS-16712 | 12/31/2023 |
| Denver | Wholesale Drug Distributor | NE | 214 | 7/1/2023 |
| Denver | Wholesale Drug Distributor | NM | WD00011290 | 12/31/2023 |
| Denver | Controlled Substances | NM | CS00216463 | 6/30/2024 |
| Denver | Category 3 Wholesale Drug Distributor (WHD + CS) | OH | 011303700 | 6/30/2023 |
| Denver | Wholesale Drug Distributor | SD | 600-0825 | 12/31/2023 |
| Denver | Controlled Substances | SD | 43166 | 7/31/2023 |
| Denver | Wholesale Drug Distributor | TX | 103678 | 2/21/2024 |
| Denver | Pharmacy Class C | UT | 12853188-1710 | 9/30/2023 |
| Denver | Controlled Substance | UT | 12853188-8913 | 9/30/2023 |
| Denver | NABP | NAPB | n/a | 12/16/2022 |
| Denver | Wholesale Drug Distributor | WY | 1139 | 6/30/2023 |
| Denver | Controlled Substances | WY | 0616ABDC09a | 6/30/2023 |

# RIDER

To be attached to and form part of:

Bond Number 08861011

dated September 20, 2006

issued by the FIDELITY AND DEPOSIT COMPANY OF MARYLAND

in the amount of $100,000.00

on behalf of AMERISOURCEBERGEN CORPORATION
(Principal)

and in favor of STATE OF NEVADA
(Obligee)

Now therefore, it is agreed that in consideration of the premium charged, the attached bond shall be amended as follows:

## LOCATION VERIFICATION:

***See Attached***

It is further understood and agreed that all other terms and conditions of this bond shall remain unchanged.

This Rider is to be Effective this 6th day of January, 2022.

Signed, Sealed & Dated this 6th day of January, 2022.

AMERISOURCEBERGEN CORPORATION
(Principal)

By: John A. Chou (Jan 12, 2022 11:14 EST)

FIDELITY AND DEPOSIT COMPANY OF MARYLAND
(Surety)

By: Sara Owens
Sara Owens, Attorney-in-Fact

The Following Address shall be Made Part of this Bond:

| | |
|---|---|
| ABDC Amityville: | 5500 New Horizon Blvd., No. Amityville, NY 11701 |
| ABDC Atlanta/Buford: | 3930 Mason Mill Rd., Buford, GA 30518 |
| ABDC Boston: | 101 Norfolk Street, Mansfield, MA 02048 |
| ABDC Chicago: | 1001 West Taylor Rd., Romeoville, IL 60446 |
| ABDC Columbus: | 6301 LaSalle Drive, Lockbourne, OH 43137 |
| ABDC Columbus: | 6305 LaSalle Dr., Lockbourne, OH 43137 |
| ABDC Corona: | 1851 California Avenue, Corona, CA 92881 |
| ABDC Dallas: | 501 Patriot Parkway, Roanoke, TX 76262 |
| ABDC: Denver: | 501 W. 44th Avenue, Denver, CO 80216 |
| ABDC Honolulu: | 238 Sand Island Access Rd. #Ml, Honolulu, HI 96819 |
| ABDC Houston: | 12727 W. Airport Blvd., Sugar Land, TX 77478 |
| ABDC Kansas City: | 11200 N. Congress Ave., Kansas City, MO 64153 |
| ABDC Kentucky: | 6001 Global Distribution Way, Suite 102, Louisville, KY 40228 |
| ABDC Morrisville: | 120 Trans Air Drive, Morrisville, NC27560 |
| ABDC Newburgh: | 108 Route 17K, Suite 1, Newburgh, NY 12550 |
| ABDC N. Amityville: | 5500 New Horizon Blvd., N. Amityville, NY 11701 |
| ABDC Olive Branch: | 12577 Stateline Road, Olive Branch, MS 38654 |
| ABDC Orlando: | 10910 Lee Vista Blvd., Suite 1, Orlando FL 32829 |
| ABDC Phoenix: | 7775 Buckeye Rd., Suite 150, Phoenix, AZ 85043 |
| ABDC Richmond: | 9900 J.E.B. Stuart Pkwy., Glen Allen, VA 23060 |
| ABDC Sacramento: | 1325 West Striker Ave., Sacramento, CA 95834 |
| ABDC Salt Lake City: | 1765 Fremont Drive., Salt Lake City, UT 84104 |
| ABDC Seattle: | 2141 S. 211th Street, Des Moines, WA 98198 |
| ABDC Shakopee: | 500 Innovation Drive, Shakopee, MN 55379 |
| ABDC Valencia: | 24903 Avenue Kearny, Valencia, CA 91355 |
| ABDC Williamston: | One Industrial Park, Williamston, MI 48895 |
| ABDC Whitestown: | 4680 Indianapolis Rd, Whitestown, IN 46075 |

| | |
|---|---|
| Theracom, LLC | 1195 Trademark Drive, #102-C, Reno, NV89511 |

| | |
|---|---|
| ASD Specialty Healthcare, LLC: | 1195 Trademark Drive, #102-A, Reno, NV 89511<br>345 International Blvd. Suite 400A, Brooks, KY 40109<br>2811 Horace Shepard Drive., Dothan, AL 36303<br>5566 Arrow Hwy, Montclair, CA 91763 |

| | |
|---|---|
| Integrated Commercialization Solutions, LLC: | 1195 Trademark Drive, #102-B Reno, NV 8951<br>6450 LaSalle Drive, Suite B/D Lockbourne, OH 43137<br>167 International Blvd., STE A, Brooks, KY 40109<br>420 International Blvd., Suite 500, Brooks, KY 4 |

## EXTRACT FROM BY-LAWS OF THE COMPANIES

"Article V, Section 8. Attorneys-in-Fact. The Chief Executive Officer, the President, or any Executive Vice President or Vice President may, by written instrument under the attested corporate seal, appoint attorneys-in-fact with authority to execute bonds, policies, recognizances, stipulations, undertakings, or other like instruments on behalf of the Company, and may authorize any officer or any such attorney-in-fact to affix the corporate seal thereto; and may with or without cause modify of revoke any such appointment or authority at any time."

## CERTIFICATE

I, the undersigned, Vice President of the ZURICH AMERICAN INSURANCE COMPANY, the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, and the FIDELITY AND DEPOSIT COMPANY OF MARYLAND, do hereby certify that the foregoing Power of Attorney is still in full force and effect on the date of this certificate; and I do further certify that Article V, Section 8, of the By-Laws of the Companies is still in force.

This Power of Attorney and Certificate may be signed by facsimile under and by authority of the following resolution of the Board of Directors of the ZURICH AMERICAN INSURANCE COMPANY at a meeting duly called and held on the 15th day of December 1998.

RESOLVED: "That the signature of the President or a Vice President and the attesting signature of a Secretary or an Assistant Secretary and the Seal of the Company may be affixed by facsimile on any Power of Attorney...Any such Power or any certificate thereof bearing such facsimile signature and seal shall be valid and binding on the Company."

This Power of Attorney and Certificate may be signed by facsimile under and by authority of the following resolution of the Board of Directors of the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY at a meeting duly called and held on the 5th day of May, 1994, and the following resolution of the Board of Directors of the FIDELITY AND DEPOSIT COMPANY OF MARYLAND at a meeting duly called and held on the 10th day of May, 1990.

RESOLVED: "That the facsimile or mechanically reproduced seal of the company and facsimile or mechanically reproduced signature of any Vice-President, Secretary, or Assistant Secretary of the Company, whether made heretofore or hereafter, wherever appearing upon a certified copy of any power of attorney issued by the Company, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

IN TESTIMONY WHEREOF, I have hereunto subscribed my name and affixed the corporate seals of the said Companies.
this 6th day of January, 2022.

Brian M. Hodges, Vice President

**TO REPORT A CLAIM WITH REGARD TO A SURETY BOND, PLEASE SUBMIT A COMPLETE DESCRIPTION OF THE CLAIM INCLUDING THE PRINCIPAL ON THE BOND, THE BOND NUMBER, AND YOUR CONTACT INFORMATION TO:**

Zurich Surety Claims
1299 Zurich Way
Schaumburg, IL 60196-1056
www.reportsfclaims@zurichna.com
800-626-4577

**ZURICH AMERICAN INSURANCE COMPANY**
**COLONIAL AMERICAN CASUALTY AND SURETY COMPANY**
**FIDELITY AND DEPOSIT COMPANY OF MARYLAND**
**POWER OF ATTORNEY**

KNOW ALL MEN BY THESE PRESENTS: That the ZURICH AMERICAN INSURANCE COMPANY, a corporation of the State of New York, the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, a corporation of the State of Illinois, and the FIDELITY AND DEPOSIT COMPANY OF MARYLAND a corporation of the State of Illinois (herein collectively called the "Companies"). by **Robert D. Murray, Vice President,** in pursuance of authority granted by Article V. Section 8, of the By-Laws of said Companies, which are set forth on the reverse side hereof and are hereby certified to be in full force and effect on the date hereof, do hereby nominate, constitute, and appoint **Wayne G. MCVAUGH, Elizabeth MARRERO, Patricia A. RAMBO, Sara OWENS, Kimberly G. SHERROD, Joanne C. WAGNER, Vicki JOHNSTON, Cathy H. HO, George GIONIS, Lori SHELTON, Jaquanda MARTIN and Kaitlyn MALKOWSKI all of Philadelphia, Pennsylvania,** EACH, its true and lawful agent and Attorney-in-Fact. to make. execute. seal and deliver, for. and on its behalf as surety, and as its act and deed: **any and all bonds and undertakings,** and the execution of such bonds or undertakings in pursuance of these presents, shall be as binding upon said Companies, as fully and amply. to all intents and purposes, as if they had been duly executed and acknowledged by the regularly elected officers of the ZURICH AMERICAN INSURANCE COMPANY at its office in New York, New York., the regularly elected officers of the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY at its office in Owings Mills, Maryland., and the regularly elected officers of the FIDELITY AND DEPOSIT COMPANY OF MARYLAND at its office in Owings Mills, Maryland., in their own proper persons.

The said Vice President does hereby certify that the extract set forth on the reverse side hereof is a true copy of Article V. Section 8. of the By-Laws of said Companies. and is now in force.

IN WITNESS WHEREOF, the said Vice-President has hereunto subscribed his/her names and affixed the Corporate Seals of the said **ZURICH AMERICAN INSURANCE COMPANY, COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, and FIDELITY AND DEPOSIT COMPANY OF MARYLAND,** this 15th day of May, A.D. 2019.

**ATTEST:**
**ZURICH AMERICAN INSURANCE COMPANY**
**COLONIAL AMERICAN CASUALTY AND SURETY COMPANY**
**FIDELITY AND DEPOSIT COMPANY OF MARYLAND**

*By: Robert D. Murray*
*Vice President*

Dawn E. Brown

*By: Dawn E. Brown*
*Secretary*

**State of Maryland**
**County of Baltimore**

On this 15th day of May, A.D. 2019, before the subscriber, a Notary Public of the State of Maryland, duly commissioned and qualified, **Robert D. Murray, Vice President and Dawn E. Brown, Secretary** of the Companies, to me personally known to be the individuals and officers described in and who executed the preceding instrument, and acknowledged the execution of same, and being by me duly sworn, deposeth and saith, that he/she is the said officer of the Company aforesaid, and that the seals affixed to the preceding instrument are the Corporate Seals of said Companies, and that the said Corporate Seals and the signature as such officer were duly affixed and subscribed to the said instrument by the authority and direction of the said Corporations.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal the day and year first above written.

Constance A. Dunn

Constance A. Dunn, Notary Public
My Commission Expires: July 9, 2019

# ABC - Nevada Surety Bond - For Licensing

Final Audit Report 2022-01-12

| | |
|---|---|
| Created: | 2022-01-12 |
| By: | Sam Smith (samuel.smith@amerisourcebergen.com) |
| Status: | Signed |
| Transaction ID: | CBJCHBCAABAAvsMj7V5jr72N62waCsrV1_k9W8RopqLi |

## "ABC - Nevada Surety Bond - For Licensing" History

Document created by Sam Smith (samuel.smith@amerisourcebergen.com)
2022-01-12 - 3:20:33 PM GMT- IP address: 163.116.157.34

Document emailed to John G. Chou (jchou@amerisourcebergen.com) for signature
2022-01-12 - 3:21:02 PM GMT

Email viewed by John G. Chou (jchou@amerisourcebergen.com)
2022-01-12 - 4:14:14 PM GMT- IP address: 107.77.204.98

Document e-signed by John G. Chou (jchou@amerisourcebergen.com)
Signature Date: 2022-01-12 - 4:14:40 PM GMT - Time Source: server- IP address: 107.77.204.98

Agreement completed.
2022-01-12 - 4:14:40 PM GMT

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of MDEG AmerisourceBergen Drug Corporation MDEG License # (if applicable) pending

Physical Address 501 W. 44th Ave.

City Denver State CO Zip 80216

Mailing Address (if different from physical address) ATTN -Legal Dept. – Licensing, 1 West First Avenue

City Conshohocken State PA Zip 19428

Telephone 815-221-3676 Website www.amerisourcebergen.com

Licensing Company Email ABDCDrugLicensing@amerisourcebergen.com

**Section 2: Personal Information**

First Zackrie Middle Joseph Phillip Last Reinhart

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] Speer Blvd.

City Denver State CO Zip 80204

Telephone [redacted] Email Zreinhart@amerisourcebergen.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✓ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| University of Arizona Global Campus | | 05/19 - 07/22 | |
| **Address** | **City** | **State** | **Zip** |
| 180 S Arion Ave Suite 301 | Chandler | AZ | 85225 |
| Diploma/Degree obtained, if any | | | |
| BA in Supply Chain Management | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Lansing Community College | | 09/16 - 01/18 | |
| **Address** | **City** | **State** | **Zip** |
| 600 N Grand Ave | Lansing | MI | 48933 |
| Diploma/Degree obtained, if any | | | |
| NA | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Flushing High School | | 09/08 - 06/12 | |
| **Address** | **City** | **State** | **Zip** |
| 5039 Deland Rd | Flushing | MI | 48433 |
| Diploma/Degree obtained, if any | | | |
| High School Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 10/01/22-Current | [redacted] Speer Blvd. | Denver | CO | 80204 |
| 02/17 - 10/21 | [redacted] Waldorf Ln | Indianapolis | IN | 46268 |
| 09/15 - 02/17 | [redacted] Coolidge Rd | East Lansing | MI | 48823 |
| 10/13 - 09/15 | [redacted] W Grand River Ave | Williamston | MI | 48895 |
| 07/93 - 10/13 | [redacted] Turner Rd | Flushing | MI | 48433 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| AmerisourceBergen Drug Corporation | | | 11/2021 - Current | |
| Business Address | | City | State | Zip |
| 501 W. 44th Ave. | | Denver | CO | 80216 |
| Phone | Title | | Number of Employed Hours | |
| 720-855-4600 | Inventory Manager | | 4240 | |
| Description of Duties | | | | |
| See attached resume | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| AmerisourceBergen Drug Corporation | | | 11/19-10/21 | |
| Business Address | | City | State | Zip |
| 4860 Indianapolis Rd. | | Whitestown | IN | 46075 |
| Phone | Title | | Number of Employed Hours | |
| (317) 769-1465 | Receiving Supervisor | | 2640 | |
| Description of Duties | | | | |
| See attached resume | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| AmerisourceBergen Drug Corporation | | | 08/17-11/19 | |
| Business Address | | City | State | Zip |
| 4860 Indianapolis Rd. | | Whitestown | IN | 46075 |
| Phone | Title | | Number of Employed Hours | |
| (317) 769-1465 | Vault/Fridge Supervisor | | 4000 | |
| Description of Duties | | | | |
| See Attached Resume | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| AmerisourceBergen Drug Corporation | | | 02/17-08/17 | |
| Business Address | | City | State | Zip |
| 4860 Indianapolis Rd. | | Whitestown | IN | 46075 |
| Phone | Title | | Number of Employed Hours | |
| (317) 769-1465 | Receiving Lead | | 960 | |
| Description of Duties | | | | |
| See attached Resume | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| | | | | |
| Phone | Title | | Number of Employed Hours | |
| | | | | |
| Description of Duties | | | | |
| | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state? | | ✓ |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline. | | ✓ |

**Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question #** N/A **. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

N/A

Original Signature (electronic, copies or stamps not accepted)

6·9·23
Date

I, Zackrie Reinhart, **certify that as the MDEG Administrator for**

AmerisourceBergen Drug Corporation,

**that I (initial that you have read and meet the following requirements):**

1. ZR Have a high school diploma or its equivalent;
2. ZR Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. ZR Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. ZR Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Zackrie Reinhart
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6.9.23
Date

| Board Use Only | Date Received: 6/15/23 |
|---|---|

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

### Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler AmerisourceBergen Drug Corporation

Pharmacy/Wholesaler License # (if applicable) n/a

Physical Address 501 W. 44th Ave.

City Denver State CO Zip 80216

Mailing Address (if different from physical address) Legal Dept. – Licensing, 1 West First Avenue

City Conshohocken State PA Zip 19428

Telephone 720-855-4600 Website www.amerisourcebergen.com

Licensing Company Email ABDCDrugLicensing@amerisourcebergen.com

### Section 2: Personal Information

First Zackrie Middle Joseph Phillip Last Reinhart

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted] Speer Blvd.

City Denver State CO Zip 80204

Telephone 720-855-4615 Email Zreinhart@amerisourcebergen.com

Are you a citizen of the United States? ■ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✓ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| University of Arizona Global Campus | | 05/19 - 07/22 | |
| **Address** | **City** | **State** | **Zip** |
| 180 S Arion Ave Suite 301 | Chandler | AZ | 85225 |
| Diploma/Degree obtained, if any | | | |
| BA in Supply Chain Management | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Lansing Community College | | 09/16 - 01/18 | |
| **Address** | **City** | **State** | **Zip** |
| 600 N Grand Ave | Lansing | MI | 48933 |
| Diploma/Degree obtained, if any | | | |
| NA | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Flushing High School | | 09/08 - 06/12 | |
| **Address** | **City** | **State** | **Zip** |
| 5039 Deland Rd | Flushing | MI | 48433 |
| Diploma/Degree obtained, if any | | | |
| High School Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 10/01/22-Current | [redacted] Speer Blvd. | Denver | CO | 80204 |
| 02/17 - 10/21 | [redacted] Waldorf Ln | Indianapolis | IN | 46268 |
| 09/15 - 02/17 | [redacted] Coolidge Rd | East Lansing | MI | 48823 |
| 10/13 - 09/15 | [redacted] W Grand River Ave | Williamston | MI | 48895 |
| 07/93 - 10/13 | [redacted] Turner Rd | Flushing | MI | 48433 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| AmerisourceBergen Drug Corporation | | | 11/2021 - Current |
| **Business Address** | **City** | **State** | **Zip** |
| 501 W. 44th Ave. | Denver | CO | 80216 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| 720-855-4600 | Inventory Manager | 4240 | |
| **Description of Duties** | | | |
| See attached resume | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| AmerisourceBergen Drug Corporation | | | 11/19-10/21 |
| **Business Address** | **City** | **State** | **Zip** |
| 4860 Indianapolis Rd. | Whitestown | IN | 46075 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| (317) 769-1465 | Receiving Supervisor | 2640 | |
| **Description of Duties** | | | |
| See attached resume | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| AmerisourceBergen Drug Corporation | | | 08/17-11/19 |
| **Business Address** | **City** | **State** | **Zip** |
| 4860 Indianapolis Rd. | Whitestown | IN | 46075 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| (317) 769-1465 | Vault/Fridge Supervisor | 4000 | |
| **Description of Duties** | | | |
| See Attached Resume | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| AmerisourceBergen Drug Corporation | | | 02/17-08/17 |
| **Business Address** | **City** | **State** | **Zip** |
| 4860 Indianapolis Rd. | Whitestown | IN | 46075 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| (317) 769-1465 | Receiving Lead | 960 | |
| **Description of Duties** | | | |
| See attached Resume | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✓ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✓ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✓ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✓ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| | | | | |
| Reason/Charge | | | | |
| | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| | | | | |
| Name of Business/Industry/Entity | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

3.7.23
Date

I, Zackrie Reinhart, **certify that as the designated representative for**

_____,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. ZR I am at least 21 years of age;
3. ZR I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ZR I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ZR I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ZR I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ZR I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Zackrie Reinhart

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3.7.23

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Zackrie Reinhart

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3.7.23

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Colorado, ss. County of Denver

I, Zackrie Reinhart, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

3.7.23

**Date**

Subscribed and Sworn to before me this 7 day of March, 2023.

**Notary Public Signature**

DAVID J DERBESY
NOTARY PUBLIC
STATE OF COLORADO
NOTARY ID 20234003278
MY COMMISSION EXPIRES 01/25/2027

# ZACKRIE REINHART

[redacted]
Zreinhart@amerisourcebergen.com
[redacted] Speer Blvd , [redacted]
Denver , CO 80204

## PROFESSIONAL SUMMARY

Skilled Inventory Manager with extensive background in pharmaceutical distribution work. Keeps teams efficient and productive by monitoring performance and effectively training new members. Expertise includes customer relations, scheduling, and records management.

## SKILLS

- Team management
- Work scheduling
- Verbal communication
- Development
- Quality assurance
- Analytical thinking
- Task prioritization

## EXPERIENCE

**Inventory Manager**, **AmerisourceBergen**, Nov 2021 - Current, Denver, CO

- Coordinated and led inventory audits to maintain accuracy and availability.
- Isolated systemic inventory problems, determined associated root causes, and implemented sustainable corrective actions that decreased shrinkage.
- Researched inventory discrepancies and adjusted to correct variances.
- Set schedules and assigned work to effectively handle different demand levels.
- Checked into customer complaints and resolved problems to maximize satisfaction and loyalty.
- Kept the distribution center operating efficiently by controlling costs and focusing on strategies for continuous improvement.
- Addressed customer concerns and complaints directly and maintained maximum satisfaction by implementing quick resolutions.

**Receiving Supervisor**, **AmerisourceBergen**, Nov 2019 - Oct 2021, Whitestown, IN

- Oversee twenty direct reports daily to meet production and accuracy standards
- Assisted and organized daily activity workflow between receiving department and production floor.
- Checked received products for damage and missing components to meet quality control standards.
- Ensure all team members are compliant with set DEA and FDA standards.
- Ensure SOP compliance.
- Handled personnel problems and complaints to restore harmony to workforce and improve teamwork.

- Set standards and expectations to be followed by all team members to ensure the expectations of both internal and external customers are met.
- Make sure all safety procedures are followed to keep all employees safe.

**Vault/Fridge Supervisor**, **AmerisourceBergen**, Aug 2017 - Nov 2019, Whitestown, IN

- Lead 15-20 associates to achieve production and accuracy standards through accountability and coaching.
- Rehearsed SOPs and demonstrated procedures to all incoming new hires and reviewed all quality errors.
- Trained in all departments to enhance ability to cross train associates rapidly in any area.
- Consistently ranked as running the top performing department in regards to both utilization ( 85-96% ) and performance (105-126% ) through labor management.
- Effectively managed departments to finish early and assist other departments in need by allocating best performers where needed for maximum throughput.

**Receiving Lead**, **AmerisourceBergen**, Feb 2017 - Aug 2017, Whitestown, IN

- Invited to come to Whitestown, IN to start up the new DC and played a crucial role in ramping up receiving, putaway by interviewing and training all associates.
- Explained the 'why' behind various rules and regulations so associates understood the reasoning and consequences of failing to uphold our standards.
- Checked received products for damage and missing components to meet quality control standards.
- Operated dollies, pallet jacks, and forklifts to move heavy loads.

**Warehouse Lead**, **AmerisourceBergen**, Jul 2015 - Feb 2017, Williamston, MI

- Deployed to various DC's in network as subject matter expert to assist in DC startups or fill in for labor shortages.
- Worked alongside team and consistently achieved production/utilization standards to demonstrate that regardless of the obstacles, it will be done.
- Brough in to help with interviews and provide a second opinion on candidates.
- Monitored employee practices and corrected teams on insufficient safety practices.

**Warehouse Associate**, **AmerisourceBergen**, Jul 2013 - Jul 2015, Williamston, MI

- Filled orders in OTC products, put up stock, rotated stock on shelves.
- Fixed errors throughout the night by using WMS and reported the offending items.
- Performed any and all tasks requested by supervisor.
- Removed trash and recyclables from work areas and disposed of according to proper procedures.
- Abided by all safety standards and OSHA regulations in warehouse environment.
- Maintained good working relationship with co-workers and management.

## EDUCATION

Bachelor of Arts, Supply Chain Management — Jun 2022

**University of Arizona Global Campus**

- GPA 3.68

# 4Y

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

**Non-Refundable $1,000 Fee**

Rev (08/17/2022)

| **Where is the facility located?** | ☐ Nevada ■ Out-of-State |
|---|---|

| **Type of Application (check applicable box)** | | **Wholesaler Business Type (check applicable box)** |
|---|---|---|
| ■ New Wholesaler<br>☐ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH _____ | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: Gemco Medical

Physical Address: 5640 Hudson Industrial Pkwy

City: Hudson State: OH Zip: 44236

Mailing Address (if different from physical address): 5640 Hudson Industrial Pkwy

City: Hudson State: OH Zip: 44236

Telephone: 800-733-7976 Website: gemcomedical.com

Name of Designated Representative (DR): Timothy Paul

Licensing Company Email: gemco.licensing@gemcomedical.com DR Email: tpaul@gemcomedical.com

| **Entities the Wholesaler will Serve (✓ all applicable)** | **Products to be Handled or Wholesaled (✓ all applicable)** | **Type of Wholesaling (✓ all applicable)** |
|---|---|---|
| ■ Pharmacies | ☐ Dangerous Drugs | ☐ Manufacturer |
| ■ Practitioners | ☐ Controlled Substances | ☐ Repacker |
| ■ Hospitals | ■ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ■ Wholesalers | ☐ Others: | ■ Warehouse |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ■ Others: DME Providers | | ☐ Others: |

| **Section 2: History of Company** | **Yes** | **No** |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✓ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | ✓ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | ✓ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✓ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

Date

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: Abbott Laboratories/Diagnostic
Address: 100 Abbott Park Road City: Abbott Park State: IL Zip: 60064

Name: Dexcom
Address: 6340 Sequence Drive City: San Diego State: CA Zip: 92121

Name: Insulet Corporation
Address: 100 Nagog Park City: Acton State: MA Zip: 01720

Name: Tandem Diabetes
Address: 11075 Roselle Street City: San Diego State: CA Zip: 92121

**Section 4: Publicly Traded Corporation**

State of Incorporation: N/A
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: Ohio
Parent Company (if any): TEMEG Holdings, Inc.
Corporation/Organization Name: GEM Edwards, Inc.
Mailing Address: 5640 Hudson Industrial Pkwy
City: Hudson State: OH Zip: 44236
Telephone: 800-733-7976 Email: gemco.licensing@gemcomedical.com
Contact Person Name: Matthew Edwards

**Section 6: Partnership**

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

**Section 7: Sole Owner**

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | ✓ | |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | | ✓ |
| 1. Copy of FDA registration<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** | | ✓ | | |
| • **List of all partners and their percent ownership.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Gemco Medical

Facility Name

Paul Tracy

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

6/27/2023

Date

| Board Use Only | Date Received: 6/28/23 | Amount: 1000-CK-73106 |
|---|---|---|

*The National Association of Boards of Pharmacy®*
*hereby awards*

*Verified-Accredited Wholesale Distributors®*
*Accreditation*
*to*

# GEM Edwards, Inc
# dba Gemco Medical

*located at*

*5640 Hudson Industrial Pkwy, Hudson, OH 44236*

*This facility has met all the Verified-Accredited Wholesale Distributors (VAWD) criteria set in place by the National Association of Boards of Pharmacy. The current status of this facility's accreditation may also be verified by visiting the VAWD section of the NABP website, located at www.nabp.pharmacy.*

Carmen A. Catizone, Executive Director/Secretary

April 5, 2019 - April 4, 2022
Period of Accreditation

National Association of Boards of Pharmacy | 1600 Feehanville Drive, Mount Prospect, IL 60056 | *www.nabp.pharmacy*

1068

NABP
National Association of Boards of Pharmacy

Main Menu

# Accredited Drug Distributors

**Find an Accredited Drug Distributor**

Facility Name

State (All)

Search Reset

Current list of 1 NABP-Accredited Drug Distributors

Verified 6.21.23 BB

Accreditation is valid for 3 years

Facilities listed with "Reaccreditation in process" remain accredited throughout the reaccreditation process.

| Name | Address | Accreditation Date |
|---|---|---|
| GEM Edwards, Inc dba Gemco Medical | 5640 Hudson Industrial Pkwy Hudson, OH 44236 | Reaccreditation in process |

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Contact



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GEMCO MEDICAL
A GEMCORE Family Company

800.733.7976

GEM Edwards, Inc. doing business as GEMCO Medical
Corporation Officers
State of Incorporation: Ohio

---

**Title: Chairman of the Board**
Name: Dee E. Edwards, Jr.

**Title: President**
Name: Paul F. Tracy

**Title: Chief Executive Officer**
Name: Matthew J. Edwards

**Title: Chief Financial Officer/Treasurer**
Name: David J. Lewis

**Title: Secretary**
Name: Aaron D. Fishbeck

**Business Address for all GEM Edwards, Inc. Officers**:
5640 Hudson Industrial Pkwy
Hudson, Ohio 44236
Business Phone: 330-342-8300

GEMCO MEDICAL
A GEMCORE Family Company

800.733.7976

GEM Edwards, Inc. doing business as GEMCO Medical
Corporate Owner
State of Incorporation: Ohio

---

**Corporate Owner:**
**TEMEG Holdings, Inc.**
100% Ownership
FEIN: 27-3454290

www.gemcomedical.com

5640 Hudson Industrial Parkway
Hudson, OH 44236

# UNITED STATES OF AMERICA
# STATE OF OHIO
# OFFICE OF THE SECRETARY OF STATE

*I, Frank LaRose, do hereby certify that I am the duly elected, qualified and present acting Secretary of State for the State of Ohio, and as such have custody of the records of Ohio and Foreign business entities; that said records show GEM EDWARDS, INC., an Ohio corporation, Charter No. 830944, having its principal location in Hudson, County of Summit, was incorporated on November 4, 1992 and is currently in GOOD STANDING upon the records of this office.*

*Witness my hand and the seal of the Secretary of State at Columbus, Ohio this 4th day of April, A.D. 2023.*

**Ohio Secretary of State**

**Validation Number:** 202309401224

STATE OF OHIO
BOARD OF PHARMACY

# LICENSE TO DISTRIBUTE DANGEROUS DRUGS

The entity named below is duly licensed, and is entitled to conduct business in the state of Ohio until June 30, 2025.

**GEMCO MEDICAL**

**5640 HUDSON INDUSTRIAL PARKWAY P.O.BOX 429**

**HUDSON, OH 44236**

**License Number: 010953100**

**Wholesaler - Category 2**

**Expiration Date: June 30, 2025**

CLASS: Wholesaler - Category 2
BUSINESS TYPE: FS – Full Service

**Responsible Person** – Print, sign and keep license in a readily retrievable location at the address listed on this license.

| Responsible Person Name (Print) | Signature of Responsible Person |
|---|---|
| Paul F. Tracy | |

*Any change of responsible person must be reported within ten days of the effective date of the appointment of the new responsible person via Service Request on your Ohio eLicense Dashboard - https://elicense.ohio.gov/oh_homepage.*

**State of Ohio Board of Pharmacy**
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

Client#: 25029 GEMCO

# ACORD™ CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 5/30/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer any rights to the certificate holder in lieu of such endorsement(s).

| PRODUCER | CONTACT NAME: Certificate Request Dept. | |
|---|---|---|
| Althans Insurance Agency, Inc.<br>543 East Washington St.<br>P.O.Box 570<br>Chagrin Falls, OH 44022 | PHONE (A/C, No, Ext): 440.247.6422 | FAX (A/C, No): 440.247.2394 |
| | E-MAIL ADDRESS: CLcerts@althans.com | |

| INSURER(S) AFFORDING COVERAGE | NAIC # |
|---|---|
| INSURER A : Massachusetts Bay Insurance | 01653 |
| INSURER B : Hanover Insurance Company | 22292 |
| INSURER C : Cincinnati Casualty Company | 28665 |
| INSURER D : Cincinnati Insurance Company | 10677 |
| INSURER E : Allmerica Financial Benefit Insurance | 41840 |
| INSURER F : | |

INSURED
GEM Edwards, Inc. dba GEMCO Medical
P.O. Box 429
Hudson, OH 44236

COVERAGES CERTIFICATE NUMBER: REVISION NUMBER:

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

| INSR LTR | TYPE OF INSURANCE | ADDL INSR | SUBR WVD | POLICY NUMBER | POLICY EFF (MM/DD/YYYY) | POLICY EXP (MM/DD/YYYY) | LIMITS | |
|---|---|---|---|---|---|---|---|---|
| A | X COMMERCIAL GENERAL LIABILITY | X | X | LDWJ-42303400 | 05/30/2023 | 05/30/2024 | EACH OCCURRENCE | $1,000,000 |
| | CLAIMS-MADE X OCCUR | | | | | | DAMAGE TO RENTED PREMISES (Ea occurrence) | $1,000,000 |
| | | | | | | | MED EXP (Any one person) | $10,000 |
| | | | | | | | PERSONAL & ADV INJURY | $1,000,000 |
| | GEN'L AGGREGATE LIMIT APPLIES PER: | | | | | | GENERAL AGGREGATE | $3,000,000 |
| | POLICY X PRO-JECT X LOC | | | | | | PRODUCTS - COMP/OP AGG | $3,000,000 |
| | OTHER: | | | | | | | $ |
| E | AUTOMOBILE LIABILITY | X | X | AWWJ-43098600 | 05/30/2023 | 05/30/2024 | COMBINED SINGLE LIMIT (Ea accident) | $1,000,000 |
| | X ANY AUTO | | | | | | BODILY INJURY (Per person) | $ |
| | OWNED AUTOS ONLY / SCHEDULED AUTOS | | | | | | BODILY INJURY (Per accident) | $ |
| | X HIRED AUTOS ONLY / X NON-OWNED AUTOS ONLY | | | | | | PROPERTY DAMAGE (Per accident) | $ |
| | | | | | | | | $ |
| B | X UMBRELLA LIAB X OCCUR | | | UHWJ-42303500 | 05/30/2023 | 05/30/2024 | EACH OCCURRENCE | $10,000,000 |
| | EXCESS LIAB CLAIMS-MADE | | | Umbrella | | | AGGREGATE | $10,000,000 |
| | DED X RETENTION $None | | | Follows Form | | | | $ |
| C | WORKERS COMPENSATION AND EMPLOYERS' LIABILITY | | | EWC-0484222 | 05/30/2023 | 05/30/2024 | X PER STATUTE / OTH-ER | |
| A | ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N N (Mandatory in NH) | N/A | | LDWJ-42303400 | 05/30/2023 | 05/30/2024 | E.L. EACH ACCIDENT | $1,000,000 |
| | If yes, describe under DESCRIPTION OF OPERATIONS below | | | Ohio Employers Liability | | | E.L. DISEASE - EA EMPLOYEE | $1,000,000 |
| | | | | | | | E.L. DISEASE - POLICY LIMIT | $1,000,000 |
| D | Data/Cyber Breach | | | EMP-0617803 | 05/30/2023 | 05/30/2024 | $3,000,000 | |

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

GEM Edwards DBA Gemco Medical
PO Box 429
Hudson, OH 44236

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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**NEVADA STATE BOARD OF PHARMACY**
**985 Damonte Ranch Pkwy Suite 206**
**Reno, NV 89521**
**(775) 850-1440**
**Fax: (775) 850-1444**

# PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 66651522

Application/License No. _____

Gemco Medical (Applicant /Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is

5640 Hudson Industrial Pkwy, Hudson, OH 44236 (Address of Applicant /Principal), as PRINCIPAL, and WESTERN SURETY COMPANY (Surety Company), a corporation organized under the laws of the state of South Dakota (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is

P.O. Box 5077, Sioux Falls, SD 57117-5077 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on May 10th, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

# Western Surety Company

## POWER OF ATTORNEY

**KNOW ALL MEN BY THESE PRESENTS:**

That WESTERN SURETY COMPANY, a corporation organized and existing under the laws of the State of South Dakota, and authorized and licensed to do business in the States of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming, and the United States of America, does hereby make, constitute and appoint

Paul T. Bruflat of Sioux Falls,
State of South Dakota, its regularly elected Vice President,
as Attorney-in-Fact, with full power and authority hereby conferred upon him to sign, execute, acknowledge and deliver for and on its behalf as Surety and as its act and deed, the following bond:

One Pharmaceutical Wholesaler

bond with bond number 66651522

for Gemco Medical
as Principal in the penalty amount not to exceed: $ 25,000.00.

Western Surety Company further certifies that the following is a true and exact copy of Section 7 of the by-laws of Western Surety Company duly adopted and now in force, to-wit:

Section 7. All bonds, policies, undertakings, Powers of Attorney, or other obligations of the corporation shall be executed in the corporate name of the Company by the President, Secretary, any Assistant Secretary, Treasurer, or any Vice President, or by such other officers as the Board of Directors may authorize. The President, any Vice President, Secretary, any Assistant Secretary, or the Treasurer may appoint Attorneys-in-Fact or agents who shall have authority to issue bonds, policies, or undertakings in the name of the Company. The corporate seal is not necessary for the validity of any bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation. The signature of any such officer and the corporate seal may be printed by facsimile.

In Witness Whereof, the said WESTERN SURETY COMPANY has caused these presents to be executed by its Vice President with the corporate seal affixed this 16th day of May, 2023.

ATTEST

L. Bauder, Assistant Secretary

WESTERN SURETY COMPANY

By Paul T. Bruflat

Paul T. Bruflat, Vice President

WESTERN SURETY COMPANY CORPORATE SEAL SOUTH DAKOTA

STATE OF SOUTH DAKOTA }
COUNTY OF MINNEHAHA } ss

On this 16th day of May, 2023, before me, a Notary Public, personally appeared Paul T. Bruflat and L. Bauder who, being by me duly sworn, acknowledged that they signed the above Power of Attorney as Vice President and Assistant Secretary, respectively, of the said WESTERN SURETY COMPANY, and acknowledged said instrument to be the voluntary act and deed of said Corporation.

M. BENT NOTARY PUBLIC SOUTH DAKOTA SEAL SEAL

M. Bent

My Commission Expires March 2, 2026

Notary Public

**To validate bond authenticity, go to www.cnasurety.com > Owner/Obligee Services > Validate Bond Coverage.**

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.

(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.

(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.

(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.

(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.

(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.

(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 16th day of May, 2023.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

WESTERN SURETY COMPANY

Surety Company's Representative

Paul T. Bruflat,
Vice President, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

NOT NEEDED
Nevada Resident Agent

Posted February 20, 2020

**NEVADA STATE BOARD OF PHARMACY**

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

# Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

## Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Gemco Medical | MDEG License # (if applicable): Applying for W

Physical Address: 5640 Hudson Industrial Pkwy

City: Hudson | State: OH | Zip: 44236

Mailing Address (if different from physical address): 5640 Hudson Industrial Pkwy

City: Hudson | State: OH | Zip: 44236

Telephone: 800-733-7976 | Website: gemcomedical.com

Licensing Company Email: gemco.licensing@gemcomedical.com

## Section 2: Personal Information

First: Timothy | Middle: Michael | Last: Paul

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] | SSN or ITIN: [redacted] | Sex: ☒ M ☐ F ☐ X

Mailing Address: 5640 Hudson Industrial Pkwy

City: Hudson | State: OH | Zip: 44236

Telephone: [redacted] | Email: tpaul@gemcomedical.com

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Kent State University | | 09/1992-05/1998 | |
| **Address** | **City** | **State** | **Zip** |
| 800 E. Summit St. | Kent | OH | 44240 |
| Diploma/Degree obtained, if any | | | |
| BA | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| Jackson High School | | 08/88-05/92 | |
| **Address** | **City** | **State** | **Zip** |
| 7600 Fulton Dr NW | Massillon | OH | 44646 |
| Diploma/Degree obtained, if any | | | |
| Diploma | | | |
| School Name | | From - To (MM/YY – MM/YY) | |
| Address | City | State | Zip |
| Diploma/Degree obtained, if any | | | |
| School Name | | From - To (MM/YY – MM/YY) | |
| Address | City | State | Zip |
| Diploma/Degree obtained, if any | | | |
| School Name | | From - To (MM/YY – MM/YY | |
| Address | City | State | Zip |
| Diploma/Degree obtained, if any | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 09/21-Present | [redacted] Partridge Meadow Dr. | Hudson | OH | 44236 |
| 06/16-09/21 | [redacted] Olenbrook Dr. | Lewis Center | OH | 43035 |
| 10/04-06/16 | [redacted] Vancouver St. | Cuyahoga Falls | OH | 44221 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Gemco Medical | | | 09/21-present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 5640 Hudson Industrial Pkwy | | Hudson | OH | 44236 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 800-733-7976 | Director of Operations | | 4096 | |

**Description of Duties**

Currently oversee all the distribution and logistics operations for a fully licensed and NABP accredited Healthcare and Medical Supply Distribution Center.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Covetrus | | | 02/16-09/21 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 3820 Twin Creeks Dr | | Columbus | OH | 43204 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 888-280-2221 | DC Manager | | 11152 | |

**Description of Duties**

Was the DR and oversaw all distribution activities of medical supplies and pharmaceuticals in a veterinary focused Distribution Center

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |

**Description of Duties**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |

**Description of Duties**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |

**Description of Duties**

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state? | | ✓ |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline. | | ✓ |

**Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>**

**This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted) Date

I, Timothy Paul, **certify that as the MDEG Administrator for**

Gemco Medical,

**that I (initial that you have read and meet the following requirements):**

1. TP Have a high school diploma or its equivalent;
2. TP Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. TP Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. TP Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Timothy Paul
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/27/2023
Date

| **Board Use Only** | Date Received: 6-28-23 |
|---|---|

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

### Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Gemco Medical

Pharmacy/Wholesaler License # (if applicable): N/A, applying for license

Physical Address: 5640 Hudson Industrial Pkwy

City: Hudson State: OH Zip: 44236

Mailing Address (if different from physical address): 5640 Hudson Industrial Pkwy

City: Hudson State: OH Zip: 44236

Telephone: 800-733-7976 Website: gemcomedical.com

Licensing Company Email: gemco.licensing@gemcomedical.com

### Section 2: Personal Information

First: Timothy Middle: Michael Last: Paul

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: 5640 Hudson Industrial Pkwy

City: Hudson State: OH Zip: 44236

Telephone: [redacted] Email: tpaul@gemcomedical.com

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Kent State University | | 09/1992-05/1998 | |
| **Address** | **City** | **State** | **Zip** |
| 800 E. Summit St. | Kent | OH | 44240 |
| **Diploma/Degree obtained, if any** | | | |
| BA | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Jackson High School | | 08/88-05/92 | |
| **Address** | **City** | **State** | **Zip** |
| 7600 Fulton Dr NW | Massillon | OH | 44646 |
| **Diploma/Degree obtained, if any** | | | |
| Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 09/21-Present | [redacted]Partridge Meadow Dr. | Hudson | OH | 44236 |
| 06/16-09/21 | [redacted]Glenbrook Dr. | Lewis Center | OH | 43035 |
| 10/04-06/16 | [redacted]Vancouver St. | Cuyahoga Falls | OH | 44221 |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Gemco Medical | | | 09/21-present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 5640 Hudson Industrial Pkwy | | Hudson | OH | 44236 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| (800) 733-7976 | Director of Operations | | 4096 | |

Description of Duties

Currently oversee all the distribution and logistics operations for a fully licensed and NABP accredited Healthcare and Medical Supply Distribution Center.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Covetrus | | | 02/16-09/21 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 3820 Twin Creeks Dr | | Columbus | OH | 43204 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| (888) 280-2221 | DC Manager | | 11152 | |

Description of Duties

Was the DR and oversaw all distribution activities of medical supplies and pharmaceuticals in a veterinary focused Distribution Center

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |

Description of Duties

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |

Description of Duties

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |

Description of Duties

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✓ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✓ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✓ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✓ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

Date

I, Timothy Paul, **certify that as the designated representative for**

Gemco Medical,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. TP I am at least 21 years of age;
3. TP I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. TP I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. TP I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. TP I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. TP I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

TIMOTHY PAUL
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/19/2023
Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

TIMOTHY PAUL

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/19/2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Ohio, ss. County of Summit

I, TIMOTHY PAUL, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

6/19/2023

**Date**

Subscribed and Sworn to before me this 19th day of June 2023.

Melissa Fouse

**Notary Public Signature**

NOTARIAL SEAL STATE OF OHIO

**MELISSA FOUSE**
**Notary Public, State of Ohio**
**My Commission Expires:**
**March 06, 2028**

**(Seal)**



MELISSA FOUSE
Notary Public, State of Ohio
My Commission Expires:
March 06, 2024

# Gemco Medical Employee List

| Employee |
| --- |
| Christineaka Vintson |
| Dawn Davet |
| Kayla Marie Moore |
| Kimberly A. Airey |
| Ruth A. McGarr |
| Alexander Tavani |
| Benjamin Lee Flower |
| John Thomas Scoarste |
| Joseph G. Ault |
| Karen Kennedy |
| Kenneth E. Spooner |
| Kevin Crum |
| Megan Coyne |
| Catherine A Klass |
| Glen Rightmire |
| Teresa Robinson |
| Chris P. Moran |
| John Tylka |
| William P. Baker |
| Ajax Joseph Locke |
| Amelia G Carpenter |
| Andrew C Jones |
| Angelica Howell |
| Anna Peeler |
| Anthony J Reale |
| Austin R Kennedy |
| Bailey Deutsch |
| Barbara Daigneau |
| Bennett Atchison |
| Beth Gump |
| Breanna G Saunders |
| Brennan Gregory |
| Brianna Marie Cole |
| Brionna Johnson |
| Catherine Ann Bielecki |
| Chalara Sutton |
| Christian Clark |
| Christopher Kaeler |
| Colin Robert Bergstrom |
| Colleen Goodrich |
| Constance Elizabeth Boller |
| Danielle Westfall |
| Darlene Ramsey |
| David Charles Japps |
| David O. Luecke |
| Dawn Fields |

# Gemco Medical Employee List

Deja'nae Wilson
Demetrius Moten
Desiree Elizabeth Hazelett
Djuana R Cooper
Dominic Shriver
Donovan Mills
Edmundo Lingat
Elaine Ann Randle
Emmah Hipsag
Eric William Sturm
Ethan Zettwoch
Fred McKendrick
Gavin McKenna
Grant Munro Orsine
Hobart Shore
Jacquelyn Jewel
James Kodadek
James Woodard
Jo Ann Colpo
Joan Milburn
John Swink
Joseph P Reaggle
Joseph Zabala
Kadence Dodds
Katerina Justice
Katherine Porter
Kennady Nicole Dodds
Kimberly Jean Sisco
Kimberly S Lanham
Klayton C Healy
Lalita Harvey
Lana Tahat
LaTasha Johnson
Latoya Churn
Luke P Keirn
Maggie Petty
Martha Krobusek
Mary Sexton
Mary Wallace
Matthew A Petush
Matthew Lau
Matthew R Adams
Meagan Suzanne Hughes
Megan Bizub
Michael P. Boal
Mikala Goodloe
Miranda York

# Gemco Medical Employee List

Mya Goodloe
Nathan Grimes
Nicholas Milicia
Randy Yommer
Rasheedah Jackson
Reno Basar
Richard Alva Chaffinch
Riley Herbert
Roderick M. Jaquias
Ronald Campbell
Ronald Slechta
Samantha Mckendrick
Samuel J Smith
Sandra Jean Benbow
Sarena Myers
Sean O. Sassa
Shannon B Carpenter
Stephanie Anderson
Stephen Edwards
Steven B. Rooth
Stuart McClendon
Sunnie A Woerner
Tammy W Damron
Timothy Paul
Tom Nahodil
Tyler Andrew Bowles
Tyler Leonardo
Victor John Victoria
Zachary T. Stutzman
Zavier Robert Lindsey-Gladney
Richard R. Keirn
Erin K. Orsine

# 4Z

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application
## Non-Refundable $1,000 Fee

Rev (08/17/2022)

| Where is the facility located? | ☐ Nevada ☑ Out-of-State |
|---|---|

| | | |
|---|---|---|
| ☑ New Wholesaler<br>☐ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH _____ | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

Facility Name: MAKS PHARMA AND DIAGNOSTICS INC.

Physical Address: 2365 MILBURN AVE, BLDG#2

City: BALDWIN State: NY Zip: 11510

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 516-323-1255 Website: MAKSPHARMA.COM

Name of Designated Representative (DR): Sadathulla Shareef

Licensing Company Email: compliance@makspharma.com DR Email: sshareef@makspharma.com

| | | |
|---|---|---|
| ☑ Pharmacies<br>☐ Practitioners<br>☐ Hospitals<br>☑ Wholesalers<br>☐ Veterinarians<br>☐ Others: | ☑ Dangerous Drugs<br>☑ Controlled Substances<br>☐ [a]Medical devices, equipment, supplies, gases<br>☐ Others: | ☐ Manufacturer<br>☐ Repacker<br>☐ Reverse Distributor<br>☑ Warehouse<br>☐ Retail pharmacy wholesale distributor<br>☐ Others: |

| | | |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✓ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | ✓ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | ✓ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✓ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # _____. **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

X _____

Original Signature (electronic, copies or stamps not accepted)

07/13/23

Date

Name: TARO PHARMACEUTICALS U.S.A. INC.

Address: 3 Skyline Drive City: Hawthorne State: NY Zip: 10532

Name: MAYNE PHARMA

Address: 650 FROM RD City: PARAMUS State: NJ Zip: 07652

Name: MCKESSON

Address: 6535 N STATE HIGHWAY City: IRVING State: TX Zip: 75039

Name: PADAGIS

Address: 1525 BATHGATE AVE City: BRONX State: NY Zip: 10457

State of Incorporation:

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

State of Incorporation/Organization: New York

Parent Company (if any):

Corporation/Organization Name: Maks Pharma and Diagnostics Inc.

Mailing Address: 2365 MILBURN AVE, BLDG#2

City: BALDWIN State: NY Zip: 11510

Telephone: 516-323-1255 Email: compliance@makspharma.com

Contact Person Name: UMMAY KHAN

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

| Section 6 (NABP Accreditation/FDA Registration) | | |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | ✓ | |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | | ✓ |
| 1. Copy of FDA registration<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |

| | | | | |
|---|---|---|---|---|
| • **List of all Officers and Directors.** | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** | | ✓ | | |
| • **List of all partners and their percent ownership.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). | ✓ | ✓ | ✓ | ✓ |
| | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Maks Pharma and Diagnostics Inc.

Facility Name

SADATHULLA SHAREEF

Print Name of Authorized Person Submitting Application

X

Original signature of Authorized Person (copies or stamps not accepted)

07/13/23

Date

| Board Use Only | Date Received: 7/26/23 | Amount: 1000-cc |
|---|---|---|

MAKSPHARMA
AND DIAGNOSTICS INC

Tel : 631-270-1528 | Fax: 866-266-1217
Admin@MaksPharma.com | www.MaksPharma.com
2365 Milburn Ave, Bldg. #2, Baldwin, NY 11510-1711

## Maks Pharma and Dignostics Inc.'s Shareholders Other Business Interests

| Name of Maks Partner/Shareholder | Percentage Held | Address | ROLE/TITLE |
|---|---|---|---|
| SADATHULLA SHAREEF | 60.00% | [redacted]EW AVENUE, HEWLETT, NY, 11557 | PRESIDENT / DESIGNATED REPRESENTATIVE |
| MOHAMEDAM HILLAL | 15.50% | [redacted]GRACE HILL ROAD, MONROE, NJ, 08831 | SHAREHOLDER/PARTNER/SALES MANAGER |
| SREEDHAR VAJINEPALLI | 7.50% | [redacted]LEAH WAY, PARSIPPANY, NJ, 07054 | SHAREHOLDER |
| MADHURI GADIRAJU | 9.00% | [redacted]OVERLOOK DR., RIVERDALE, NJ, 07457 | SHAREHOLDER |
| MEHULKUMAR PATEL | 2.50% | [redacted]ALMETTO DR., EASTON, PA, 18045 | SHAREHOLDER |
| MANU KAKAR | 1.83% | [redacted]CARINGE ST, MONROE, NJ, 08873 | SHAREHOLDER |
| REINALDO CEDENO | 1.83% | [redacted]VANCE AVE, FRANKLIN LAKES, NJ, 07417 | SHAREHOLDER |
| RENE DEHOMBRE | 1.83% | [redacted]LONE CEDAR WAY, OLD TAPPAN, NJ, 07675 | SHAREHOLDER |
| TOTAL | 100% | | |

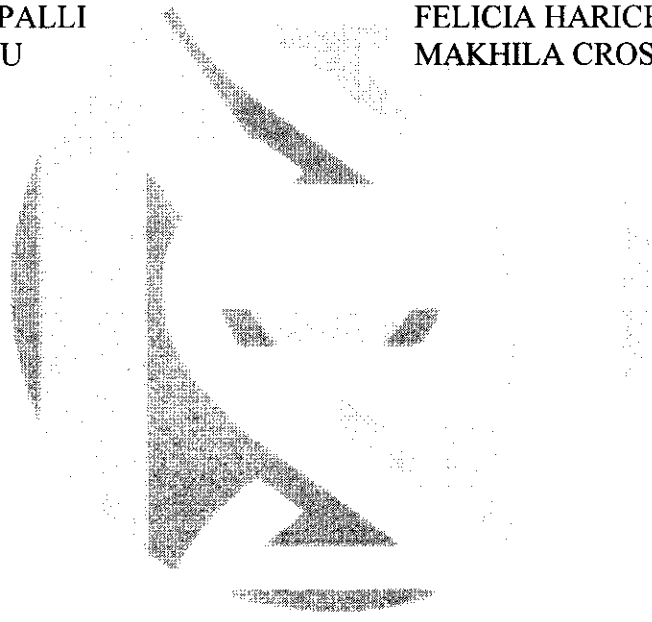
MAKSPHARMA
AND DIAGNOSTICS INC

## OWNERS

AMR HILAL
ATIQ REHMAN
MADHURI GADIRAJU
MANU KAKAR
MEHUL KUMAR PATEL
QUADRATULLA SHAREEF
REINALDO CEDENO
RENE DEHOMBRE
SREEDHAR VAJINEPALLI
SRINIVAS GADIRAJU

## EMPLOYEES

UMMAY KHAN
NUR KHAN
ARHAM KHAN
NAVNEET KAUR
MAZHAR ALI
MASOOD ARIF
IRUM SALMAN
HAZEM MAKKAWI
FELICIA HARICHAND
MAKHILA CROSLEY



**STATE OF NEW YORK**

**DEPARTMENT OF STATE**

**Certificate of Status**

I, ROBERT J. RODRIGUEZ, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

| | |
|---|---|
| **Entity Name:** | MAKS PHARMA AND DIAGNOSTICS INC. |
| **DOS ID Number:** | 4286892 |
| **Entity Type:** | DOMESTIC BUSINESS CORPORATION |
| **Entity Status:** | EXISTING |
| **Date of Initial Filing with DOS:** | 08/22/2012 |
| **Statement Status:** | CURRENT |
| **Statement Due Date:** | 08/31/2022 |

No information is available from this office regarding the financial condition, business activity or practices of this entity.




WITNESS my hand and official seal of the Department of State, at the City of Albany, on July 19, 2023 at 06:59 A.M.

ROBERT J. RODRIGUEZ, Secretary of State

Brendan C. Hughes

By Brendan C. Hughes
Executive Deputy Secretary of State

Authentication Number: 100003954870 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

# THE UNIVERSITY OF THE STATE OF NEW YORK
# EDUCATION DEPARTMENT

# NEW YORK STATE BOARD OF PHARMACY

2022-25

NAME OF SUPERVISOR
SADATH SHAREEF

THIS IS TO CERTIFY

MAKS PHARMA AND DIAGNOSTICS INC.
2365 MILBURN AVE.
BLDG. #2
BALDWIN, NY 11510-1711

is duly recorded as a

## REGISTERED WHOLESALER OF DRUGS AND/OR DEVICES

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE FIRST DAY OF FEBRUARY, 2022.
THIS CERTIFICATE EXPIRES ON THE THIRTY-FIRST DAY OF JANUARY, 2025.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER

031584

EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

1105

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| RM0504212 | 01-31-2024 | $1850 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N,3, 3N,4,5 | DISTRIBUTOR | 01-26-2023 |

MAKS PHARMA AND DIAGNOSTICS, INC.
2365 MILBURN AVE
BLDG 2
BALDWIN, NY 115103349

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

**THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.**

---

**CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE**
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| RM0504212 | 01-31-2024 | $1850 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N,3, 3N,4,5 | DISTRIBUTOR | 01-26-2023 |

MAKS PHARMA AND DIAGNOSTICS, INC.
2365 MILBURN AVE
BLDG 2
BALDWIN, NY 115103349

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| RM0504212 | 01-31-2024 | $1850 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N,3, 3N,4,5 | DISTRIBUTOR | 01-26-2023 |

MAKS PHARMA AND DIAGNOSTICS, INC.
2365 MILBURN AVE
BLDG 2
BALDWIN, NY 115103349

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

**THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.**

Form DEA-223/511 (9/2016)

**REPORT**

**CHANGES**

**PROMPTLY**

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:
   **Drug Enforcement Administration**
   **P.O. Box 2639**
   **Springfield, VA 22152-2639**

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

Drug Codes
2012

# NABP ACCREDITED
## DRUG DISTRIBUTOR

Maks Pharma and Diagnostics Inc

located at

2365 Milburn Avenue, Bldg 2, Baldwin, NY 11510

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

**Lemrey "Al" Carter,** PharmD, MS, RPh
*Executive Director/Secretary*

9/14/2020 - 9/13/2023
Period of Accreditation

NABP
National Association of Boards of Pharmacy

847/391-4406
Fax: 847/375-1114

1600 Feehanville Dr
Mount Prospect, IL 60056
help@nabp.pharmacy

September 11, 2020

Sadathulla Shareef
Maks Pharma and Diagnostics Inc
2365 Milburn Avenue, Bldg 2
Baldwin, NY 11510

Dear Mr Shareef:

On behalf of the National Association of Boards of Pharmacy® (NABP®) and Drug Distributor Accreditation staff, thank you for the hospitality extended to Kenny Rodgers during the recent survey.

Information provided by the surveyor indicates your facility is operating in compliance with program criteria. NABP will now conduct a final assessment of all application materials, survey findings, and responses to confirm your facility meets Drug Distributor Accreditation criteria. The Accreditation Committee will then render a decision whether to accredit.

Direct questions to vawd@napb.pharmacy or 847/391-4539.

Best Regards,

Dawn Bibbs-Morrissey
Senior Manager, Distribution Programs

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

Name of Pharmacy/Wholesaler Maks Pharma and Diagnostics Inc.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 2365 Milburn Avenue Building 2

City Baldwin State NY Zip 11510

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

First Sadathulla Middle _____ Last Shareef

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] Kew Avenue

City Hewlett State NY Zip 11557

Telephone [redacted] Email sshareef@makspharma.com

Are you a citizen of the United States? ☑ Yes ☐ No

| | | |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| | | |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

| School Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Jadavapur University | | | 1991-1993 | |
| Address | | City | State | Zip |
| kolkata, India | | | | |
| Diploma/Degree obtained, if any | | | | |
| Master of Technology (BIOTECHNOLOGY) | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| Kakatiya University | | | 1985-1989 | |
| Address | | City | State | Zip |
| Warangal, India | | | | |
| Diploma/Degree obtained, if any | | | | |
| Bachelor of Pharmacy | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |
| School Name | | | From - To (MM/YY – MM/YY | |
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 2/2009-Present | [redacted]ew Avenue | Hewlett | NY | 11557 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Maks Pharma and Diagnostics Inc. | | | 10/2012-present |
| **Business Address** | **City** | **State** | **Zip** |
| 2365 Milburn Ave, Bldg #2 | Baldwin | NY | 11510 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| 516-323-1255 | | 20,800 | |

**Description of Duties**
Developing high quality business strategies and plans ensuring their alignment with short-term and long-term objectives
Leading and motivating subordinates to advance employee engagement develop a high performing managerial team
Overseeing all operations and business activities to ensure they produce the desired results and are consistent with the

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| AAA Drugs Inc. | | | 04/2015-12/2018 |
| **Business Address** | **City** | **State** | **Zip** |
| 143-73 243rd St | Rosedale | NY | 11422 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| 718-528-5299 | Part-time Pharmacist | | |

**Description of Duties**
Prepare medications by reviewing and interpreting physician orders
Detecting therapeutic incompatibilities
Dispensing medications by compounding, packaging, and labeling pharmaceuticals

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Mediciti Drugs Inc. | | | 02/2010-04/2015 |
| **Business Address** | **City** | **State** | **Zip** |
| 389 Onderdonk Ave | Ridgewood | NY | 11385 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| 718-381-3622 | Pharmacist | | |

**Description of Duties**
Filling of prescriptions
Instructing and advising patients
Consult with doctors

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Olshin's Pharmacy | | | 07/2007-02/2010 |
| **Business Address** | **City** | **State** | **Zip** |
| 114 Congress St | Newark | NJ | 07105 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| 973-344-9000 | Pharmacist | | |

**Description of Duties**
Fill prescriptions, verifying instructions from physicians on the proper amounts of medication to give to patients
Check whether the prescription will interact negatively with other drugs that a patient is taking or any medical conditions the patient has

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Stanbio Laboratory | | | 06/2003-07/2006 |
| **Business Address** | **City** | **State** | **Zip** |
| 1261 N Main St | Boerne | TX | 78006 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | Production Manager | | |

**Description of Duties**
Supervision of day to day activities of various departments:
Packaging, Manufacturing, Warehouse, Purchasing, and Shipping/ Receiving.
Production Planning and Scheduling

Continue on next page if additional space is needed.

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| | | |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✓ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✓ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✓ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✓ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

X _____

Original Signature (electronic, copies or stamps not accepted)

07/13/23

Date

I, Sadathulla Shareef, **certify that as the designated representative for**

Maks Pharma and Diagnostics Inc.,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. S.S I am at least 21 years of age;
3. S.S I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. S.S I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. S.S I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. S.S I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. S.S I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Sadathulla Shareef

Print Name (First, Last)

X

Original Signature (electronic, copies or stamps not accepted)

07/13/23

Date

Type text here

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

8985 Milbank Avenue Building 2

Sadathulla Shareef

Print Name (First, Last)

X _____

Original Signature (electronic, copies or stamps not accepted)

Date X 07/13/23

---

**Please have this section completed in the presence of a Notary Public.**

State of New York, ss. County of Nassau

I, Sadathulla Shareef, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

_____

**Original Signature**

07/13/23

**Date**

Subscribed and Sworn to before me this 13 day of July 2023.

_____

**Notary Public Signature**

UMMAY HABIBA KHAN
Notary Public - State of New York
No. 01KH6446540
Qualified in Kings County
My Commission Expires 1/23/27

(Seal)

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/18/2023)

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Maks Pharma and Diagnostics INC.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 2365 MILBURN AVE BLDG# 2

City BALDWIN State NY Zip 11510

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 516-323-1255 Website MAKSPHARMA.COM

Licensing Company Email COMPLIANCE@MAKSPHARMA.COM

First SADATHULLA Middle _____ Last SHAREEF

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITI [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] KEW AVE

City HEWLETT State NY Zip 11557

Telephone [redacted] Email SSHAREEF@MAKSPHARMA.COM

Are you a citizen of the United States? ☑ Yes ☐ No

| | | |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| | | |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

S.S

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| JADAVAPUR UNIVERSITY | | 1991-1993 | |
| Address | City | State | Zip |
| KOLKATA, INDIA | | | |
| Diploma/Degree obtained, if any | | | |
| MASTER OF TECHNOLOGY (BIOTECHNOLOGY) | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| KAKATIYA UNIVERSITY | | 1985-1989 | |
| Address | City | State | Zip |
| WARANGAL, INDIA | | | |
| Diploma/Degree obtained, if any | | | |
| BACHELOR OF PHARMACY | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 02/2009-PRESENT | [redacted]KEW AVE | HEWLETT | NY | 11557 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
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| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
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| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
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| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |

S.S

| Business Name | From - To (MM/YY – MM/YY) |
|---|---|
| MAKS PHARMA AND DIAGNOSTICS INC. | 10/2012-PRESENT |

| Business Address | City | State | Zip |
|---|---|---|---|
| 2765 MILBURN AVE BLDG# 2 | BALDWIN | NY | 11510 |

| Phone | Title |
|---|---|
| 516-323-1255 | PRESIDENT |

Description of Duties

DEVELOPING HIGH QUALITY BUSINESS STRATEGIES AND PLANS ALIGNING WITH SHORT-TERM AND LONG-TERM OBJECTIVES. BEING A LEADER AND MOTIVATOR TO MAINTAIN A PRODUCTIVE TEAM

| Business Name | From - To (MM/YY – MM/YY) |
|---|---|
| AAA DRUGS INC | 04/2015-12/2018 |

| Business Address | City | State | Zip |
|---|---|---|---|
| 143-73 243RD ST | ROSEDALE | NY | 11422 |

| Phone | Title |
|---|---|
| 718-528-5299 | PART-TIME PHARMACIST |

Description of Duties

PREPARING MEDICATIONS ACCORDING TO PHYSICIANS ORDERS
DETECTING THERAPEUTIC INCOMPATIBILITIES/ DISPENSING MEDICATIONS BY COMPOUNDING & PACKAGING

| Business Name | From - To (MM/YY – MM/YY) |
|---|---|
| | |

| Business Address | City | State | Zip |
|---|---|---|---|
| | | | |

| Phone | Title |
|---|---|
| | |

Description of Duties

| Business Name | From - To (MM/YY – MM/YY) |
|---|---|
| | |

| Business Address | City | State | Zip |
|---|---|---|---|
| | | | |

| Phone | Title |
|---|---|
| | |

Description of Duties

| Business Name | From - To (MM/YY – MM/YY) |
|---|---|
| | |

| Business Address | City | State | Zip |
|---|---|---|---|
| | | | |

| Phone | Title |
|---|---|
| | |

Description of Duties

Continue on next page if additional space is needed.

S.S

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

S.S

| | | |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✔ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

S.S

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| Reason/Charge | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| Name of Business/Industry/Entity | | | | |

**Provide explanation below:**

X _____

Original Signature (electronic, copies or stamps not accepted)

07/17/23

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

SADATHULLA SHAREEF

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/17/23

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of New York, ss. County of Nassau

I, Sadathulla Shareef, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

07/13/23

**Date**

Subscribed and Sworn to before me this 13 day of July 2023.

**Notary Public Signature**

UMMAY HABIBA KHAN
Notary Public - State of New York
No. 01KH6446540
Qualified in Kings County
My Commission Expires 1/23/27

(Seal)

S.S

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/18/2023)

### Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Maks Pharma and Diagnostics Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 2365 MILBURN AVE, BLDG#2

City: BALDWIN State: NY Zip: 11510

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 516-323-1255 Website: MAKSPHARMA.COM

Licensing Company Email: compliance@makspharma.com

### Section 2: Personal Information

First: MOHAMEDAM Middle: SAMMY Last: HILLAL

Alias(es, nicknames, name changes, etc.): AMR HILLAL

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Grace Hill Road

City: MONROE State: NJ Zip: 08831

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| LONG ISALND UNIVERSITY | | 1996-2001 | |
| Address: 1 UNIVERSITY PLAZA | City | State | Zip |
| Diploma/Degree obtained, if any | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| ABRAHAM CLARK HIGH SCHOOL | | 1992-1996 | |
| Address: 122 E 6TH AVE | City: ROSELLE | State: NJ | Zip: 07203 |
| Diploma/Degree obtained, if any | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| Diploma/Degree obtained, if any | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| Diploma/Degree obtained, if any | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| Diploma/Degree obtained, if any | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 2005-PRESENT | [redacted] Grace Hill Road | Monroe | NJ | 08831 |
| 1985-2005 | [redacted] E 4TH AVE | ROSELLE | NJ | 07203 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| TEXAS ROAD PHARMACY | | | 2003-PRESENT | |
| **Business Address** | | **City** | **State** | **Zip** |
| 1183 ENGLISH TOWN ROAD | | OLD BRIDGE | NJ | 08857 |
| **Phone** | **Title** | | | |
| 732-723-1101 | OWNER/PHARMACIST IN CHARGE | | | |
| **Description of Duties** | | | | |
| MANAGING PHARMACY OPERATIONS<br>ENSURING ADHERENCE TO STATE AND FEDERAL REGULATIONS<br>DIRECTLY SUPERVISE PHARMACISTS AND TECHNICIANS | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| SPOTSWOOD PHARMACY | | | 02/2020- PRESENT | |
| **Business Address** | | **City** | **State** | **Zip** |
| 14 SNOWHILL ST | | SPOTSWOOD | NJ | 08884 |
| **Phone** | **Title** | | | |
| 732-955-6060 | OWNER | | | |
| **Description of Duties** | | | | |
| MANAGING PHARMACY OPERATIONS<br>ENSURING ADHERENCE TO STATE AND FEDERAL REGULATIONS<br>DIRECTLY SUPERVISING PHARMACISTS AND TECHNICIANS | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| THE PHARMACY AT BELL WORKS | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| 101 CRAWFORDS CORDER RD, STE 116-C | | HOLMDEL | NJ | 07733 |
| **Phone** | **Title** | | | |
| 732-285-4064 | OWNER | | | |
| **Description of Duties** | | | | |
| MANAGING PHARMACY OPERATIONS<br>ENSURING ADHERENCE TO STATE AND FEDERAL REGULATIONS<br>DIRECTLY SUPERVISING PHARMACISTS AND TECHNICIANS | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✓ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✓ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✓ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✓ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| Reason/Charge | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| Name of Business/Industry/Entity | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

Date 1/13/23

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Mohamedam Hillal

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/13/2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of NEW YORK, ss. County of NASSAU

I, Mohamedam Hillal, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

7/13/2023

**Date**

Subscribed and Sworn to before me this 13 day of July 2023.

**Notary Public Signature**

UMMAY HABIBA KHAN
Notary Public - State of New York
No. 01KH6446540
Qualified in Kings County
My Commission Expires 1/23/27

(Seal)

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

## PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. PB02671702198

Application/License No. _____

Maks Pharma & Diagnostics Inc (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 2365 Milburn Ave, Bldg #2, Baldwin, NY 11510 (Address of Applicant/Principal), as PRINCIPAL, and PHILADELPHIA INDEMNITY INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of PA (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is ONE BALA PLAZA SUITE 100 BALA CYNWYD, PA 19004 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 10/27/2021 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 27th day of October, 2021.

APPLICANT/PRINCIPAL

COMPANY

Authorized Representative

SURETY

Surety Company's Representative

Valerie Ann Aber, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

A NOTARY PUBLIC OR OTHER OFFICER COMPLETING THIS CERTIFICATE VERIFIES ONLY THE IDENTITY OF THE INDIVIDUAL WHO SIGNED THE DOCUMENT TO WHICH THIS CERTIFICATE IS ATTACHED, AND NOT THE TRUTHFULNESS, ACCURACY, OR VALIDITY OF THAT DOCUMENT

STATE OF ARIZONA
COUNTY OF MARICOPA } SS.

ON 12/27/2021 BEFORE ME, Joshua Ferman

PERSONALLY APPEARED Valerie Ann Aber, ATTORNEY-IN-FACT

WHO PROVED TO ME ON THE BASIS OF SATISFACTORY EVIDENCE TO BE THE PERSON(S) WHOSE NAME(S) IS/ARE SUBSCRIBED TO THE WITHIN INSTRUMENT AND ACKNOWLEDGED TO ME THAT HE/SHE/THEY EXECUTED THE SAME IN HIS/HER/THEIR AUTHORIZED CAPACITY(IES) AND THAT BY HIS/HER/THEIR SIGNATURE(S) ON THE INSTRUMENT THE PERSON(S), OR THE ENTITY UPON BEHALF OF WHICH THE PERSON(S) ACTED, EXECUTED THE INSTRUMENT.

I CERTIFY UNDER PENALTY OF PERJURY UNDER THE LAWS OF THE STATE OF ARIZONA THAT THE FOREGOING PARAGRAPH IS TRUE AND CORRECT.

*WITNESS MY HAND AND OFFICIAL SEAL.*

*SIGNATURE* _____

JOSHUA FERMAN
Notary Public - State of Arizona
MARICOPA COUNTY
Commission # 561267
Expires April 12, 2023

*THIS AREA FOR OFFICIAL NOTORIAL SEAL*

**PHILADELPHIA INDEMNITY INSURANCE COMPANY**
One Bala Plaza, Suite 100
Bala Cynwyd, PA 19004-0950

**Power of Attorney**

KNOW ALL PERSONS BY THESE PRESENTS: That **PHILADELPHIA INDEMNITY INSURANCE COMPANY** (the Company), a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, does hereby constitute and appoint Valerie Ann Aber and Daniel Rivera of Worldwide Insurance Specialists, Inc. its true and lawful Attorney-in-fact with full authority to execute on its behalf bonds, undertakings, recognizances and other contracts of indemnity and writings obligatory in the nature thereof, issued in the course of its business and to bind the Company thereby, in an amount not to exceed $50,000,000.

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of PHILADELPHIA INDEMNITY INSURANCE COMPANY on the 14th of November, 2016.

**RESOLVED:** That the Board of Directors hereby authorizes the President or any Vice President of the Company: (1) Appoint Attorney(s) in Fact and authorize the Attorney(s) in Fact to execute on behalf of the Company bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof and to attach the seal of the Company thereto; and (2) to remove, at any time, any such Attorney-in-Fact and revoke the authority given. And, be it

**FURTHER RESOLVED:** That the signatures of such officers and the seal of the Company may be affixed to any such Power of Attorney or certificate relating thereto by facsimile, and any such Power of Attorney so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking to which it is attached.

IN TESTIMONY WHEREOF, PHILADELPHIA INDEMNITY INSURANCE COMPANY HAS CAUSED THIS INSTRUMENT TO BE SIGNED AND ITS CORPORATE SEALTO BE AFFIXED BY ITS AUTHORIZED OFFICE THIS 5TH DAY OF MARCH, 2021.

(Seal)

John Glomb, President & CEO
Philadelphia Indemnity Insurance Company

On this 5th day of March, 2021 before me came the individual who executed the preceding instrument, to me personally known, and being by me duly sworn said that he is the therein described and authorized officer of the **PHILADELPHIA INDEMNITY INSURANCE COMPANY**; that the seal affixed to said instrument is the Corporate seal of said Company; that the said Corporate Seal and his signature were duly affixed.

Commonwealth of Pennsylvania - Notary Seal
Vanessa Mckenzie, Notary Public
Montgomery County
My commission expires November 3, 2024
Commission number 1308304
Member, Pennsylvania Association of Notaries

Notary Public: Vanessa McKenzie

residing at: Bala Cynwyd, PA

My commission expires: November 3, 2024

I, Edward Sayago, Corporate Secretary of PHILADELPHIA INDEMNITY INSURANCE COMPANY, do hereby certify that the foregoing resolution of the Board of Directors and the Power of Attorney issued pursuant thereto on the 5th day March, 2021 are true and correct and are still in full force and effect. I do further certify that John Glomb, who executed the Power of Attorney as President, was on the date of execution of the attached Power of Attorney the duly elected President of PHILADELPHIA INDEMNITY INSURANCE COMPANY.

In Testimony Whereof I have subscribed my name and affixed the facsimile seal of each Company this 27th day of October, 20 21.

Edward Sayago, Corporate Secretary
**PHILADELPHIA INDEMNITY INSURANCE COMPANY**

# 4AA

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

**Non-Refundable $1,000 Fee**

Rev (08/17/2022)

| Where is the facility located? | ☐ Nevada ☒ Out-of-State |
|---|---|

| Type of Application (check applicable box) | | Wholesaler Business Type (check applicable box) |
|---|---|---|
| ☐ New Wholesaler<br>☒ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH WH01327 | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: Apotex Corp.

Physical Address: 2516 Airwest Boulevard

City: Plainfield State: IN Zip: 46168

Mailing Address (if different from physical address): 2516 Airwest Boulevard

City: Plainfield State: IN Zip: 46168

Telephone: (317) 839-6550 Website: www.apotex.com/us/en/

Name of Designated Representative (DR): Jeremy Rollins

Licensing Company Email: sshaikh@apotexcorp.com DR Email: jrollins@apotexcorp.com

| Entities the Wholesaler will Serve (✓ all applicable) | Products to be Handled or Wholesaled (✓ all applicable) | Type of Wholesaling (✓ all applicable) |
|---|---|---|
| ☑ Pharmacies | ☑ Dangerous Drugs | ☑ Manufacturer |
| ☐ Practitioners | ☑ Controlled Substances | ☐ Repacker |
| ☑ Hospitals | ☐ *Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ☑ Wholesalers | ☑ Others: OTC | ☐ Warehouse |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ☑ Others: mail-order, govt., institutional managed care | | ☐ Others: |

| Section 2: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | x |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | x |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | x |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | x |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | x |

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

**Section 4: Publicly Traded Corporation**

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: DE

Parent Company (if any): Aposherm Delaware Holdings Corp

Corporation/Organization Name: Apotex Corp.

Mailing Address: 2516 Airwest Boulevard

City: Plainfield State: IN Zip: 46168

Telephone: (317) 839-6550 Email: sshaikh@apotexcorp.com

Contact Person Name: Jeremy Rollins

**Section 6: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

**Section 7: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question #** N/A **. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | x | |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | | x |
| 1. Copy of FDA registration<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** | | ✓ | | |
| • **List of all partners and their percent ownership.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Apotex Corp.
Facility Name

Kiran Krishnan
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

4/6/2023
Date

| Board Use Only | Date Received: 4-19-23 | Amount: 1000.00 CK - 18383 |
|---|---|---|

APOTEX
ADVANCING GENERICS

## Description of Operations

Apotex Corp. ("Apotex") operates as a captive distributor of its own-labeled non-controlled legend drugs, Schedules III, IIIN, IV, & V controlled legend drugs, and OTC drugs. Their affiliate company Apotex Inc. holds the ANDA/NDAs for Apotex's labeled products. Apotex is wholly owned by parent company Apotex Delaware Holdings Corp.

The licensed facility is 156,000 sq. ft. (including 5,000 sq. ft. of office space). Currently, the licensed facility operates multiple shifts with the hours of operation being Sunday 10:30pm-12:00am, Monday through Thursday open 24-hours (12:00am – 11:59pm), Friday 12:00am – 10:30pm, Saturdays Closed. Customers consist of hospitals, clinics, wholesalers, distributors, retail chain drug stores, mail-order, government, and institutional managed care facilities. This facility does not ship directly to the end user.

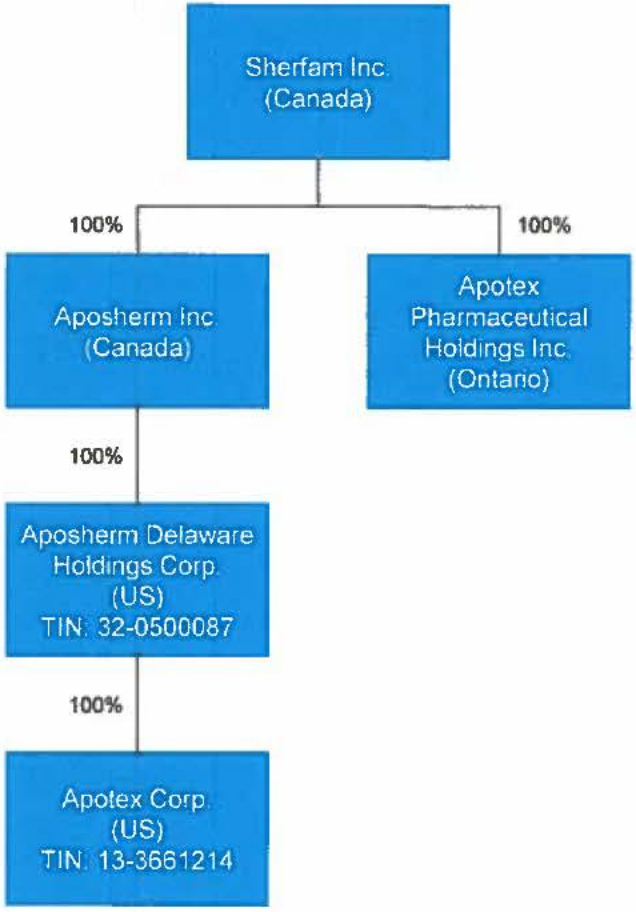
Security at the licensed facility consists of a DEA approved cage storage area for the controlled substances. There are 33 security cameras located throughout the facility. This includes 7 exterior cameras, 4 inside the controlled substance cage, and 4 cameras are located directly outside of the controlled substance cage. There are 77 PIR sensors throughout the facility which trigger their alarm. This includes 12 PIR sensors inside the DEA cage which trigger the alarm. There are 5 glass break sensors (one in each room with an exterior window) which trigger the alarm. The licensed facility is monitored 24 hours per day, 7 days per week by Stanley Convergent Security Solutions.

Label Code: 60505

See attached supplemental list of manufacturers of Apotex's products.

Apotex Corp. 2516 Airwest Boulevard Plainfield IN 46168
Tel: (317) 839-6550 Fax: (317) 839-6240
www.apotex.com/us/en

## Pre-Closing Org Chart




## Post-Closing Org Chart



NABP
National Association of Boards of Pharmacy

Main Menu

# Accredited Drug Distributors

**Find an Accredited Drug Distributor**

UAWD

Facility Name

State (All)

Search Reset

## Current list of 1 NABP-Accredited Drug Distributors

Accreditation is valid for 3 years

Facilities listed with "Reaccreditation in process" remain accredited throughout the reaccreditation process.

| Name | Address | Accreditation Date |
|---|---|---|
| Apotex Corp | 2516 Airwest Blvd<br>Plainfield, IN 46168 | 08/06/21 |

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Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

# National Drug Code Directory

Current through March 15, 2023

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Search Results: 'apotex'

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CSV Excel

Display All records per page

Search for text in the table:

| Proprietary Name | NDC Package Code | Strength | Dosage Form | Route | Appl. No. | Labeler Name | Product NDC | Nonproprietary Name | Substance Name | Product Type |
|---|---|---|---|---|---|---|---|---|---|---|
| abiraterone acetate | 60505-4764-0 | 500 mg/1 | TABLET, FILM COATED | ORAL | ANDA212442 | Apotex Corp. | 60505-4764 | Abiraterone acetate | ABIRATERONE ACETATE | HUMAN PRESCRIPTION DRUG |
| Abiraterone Acetate | 60505-4317-1 | 250 mg/1 | TABLET | ORAL | ANDA208453 | Apotex Corp. | 60505-4317 | Abiraterone Acetate | ABIRATERONE ACETATE | HUMAN PRESCRIPTION DRUG |
| acyclovir | 60505-3806-3 | 400 mg/1 | TABLET | ORAL | ANDA077309 | Apotex Corp. | 60505-3806 | acyclovir | ACYCLOVIR | HUMAN PRESCRIPTION DRUG |
| acyclovir | 60505-3806-1 | 400 mg/1 | TABLET | ORAL | ANDA077309 | Apotex Corp. | 60505-3806 | acyclovir | ACYCLOVIR | HUMAN PRESCRIPTION DRUG |
| acyclovir | 60505-3807-1 | 800 mg/1 | TABLET | ORAL | ANDA077309 | Apotex Corp. | 60505-3807 | acyclovir | ACYCLOVIR | HUMAN PRESCRIPTION DRUG |
| acyclovir | 60505-3807-3 | 800 mg/1 | TABLET | ORAL | ANDA077309 | Apotex Corp. | 60505-3807 | acyclovir | ACYCLOVIR | HUMAN PRESCRIPTION DRUG |
| acyclovir | 60505-3807-5 | 800 mg/1 | TABLET | ORAL | ANDA077309 | Apotex Corp. | 60505-3807 | acyclovir | ACYCLOVIR | HUMAN PRESCRIPTION DRUG |
| ACYCLOVIR | 60505-0043-5 | 200 mg/1 | CAPSULE | ORAL | ANDA075677 | Apotex Corp. | 60505-0043 | ACYCLOVIR | ACYCLOVIR | HUMAN PRESCRIPTION DRUG |
| acyclovir | 60505-3806-5 | 400 mg/1 | TABLET | ORAL | ANDA077309 | Apotex Corp. | 60505-3806 | acyclovir | ACYCLOVIR | HUMAN PRESCRIPTION DRUG |
| acyclovir | 60505-3806-8 | 400 mg/1 | TABLET | ORAL | ANDA077309 | Apotex Corp. | 60505-3806 | acyclovir | ACYCLOVIR | HUMAN PRESCRIPTION DRUG |
| ACYCLOVIR | 60505-0043-8 | 200 mg/1 | CAPSULE | ORAL | ANDA075677 | Apotex Corp. | 60505-0043 | ACYCLOVIR | ACYCLOVIR | HUMAN PRESCRIPTION DRUG |
| Adefovir dipivoxil | 60505-2947-0 | 10 mg/1 | TABLET | ORAL | ANDA202419 | Apotex Corp. | 60505-2947 | adefovir dipivoxil | ADEFOVIR DIPIVOXIL | HUMAN PRESCRIPTION DRUG |
| Ambrisentan | 60505-4532-3 | 5 mg/1 | TABLET, FILM COATED | ORAL | ANDA218701 | Apotex Corp. | 60505-4532 | AMBRISENTAN | AMBRISENTAN | HUMAN PRESCRIPTION DRUG |

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| Proprietary Name | NDC Package Code | Strength | Dosage Form | Route | Appl. No. | Labeler Name | Product NDC | Nonproprietary Name | Substance Name | Product Type |
|---|---|---|---|---|---|---|---|---|---|---|
| Ambrisentan | 60505-4553-1 | 10 mg/1 | TABLET, FILM COATED | ORAL | ANDA218701 | Apotex Corp. | 60505-4553 | AMBRISENTAN | AMBRISENTAN | HUMAN PRESCRIPTION DRUG |
| Amlodipine and Atorvastatin | 60505-3478-3 | 5 mg/1, 10 mg/1 | TABLET, FILM COATED | ORAL | ANDA205199 | Apotex Corp. | 60505-3478 | Amlodipine and Atorvastatin | AMLODIPINE BESYLATE; ATORVASTATIN CALCIUM TRIHYDRATE | HUMAN PRESCRIPTION DRUG |
| Amlodipine and Atorvastatin | 60505-3479-3 | 10 mg/1, 10 mg/1 | TABLET, FILM COATED | ORAL | ANDA205199 | Apotex Corp. | 60505-3479 | Amlodipine and Atorvastatin | AMLODIPINE BESYLATE; ATORVASTATIN CALCIUM TRIHYDRATE | HUMAN PRESCRIPTION DRUG |
| Amlodipine and Atorvastatin | 60505-3483-3 | 5 mg/1, 20 mg/1 | TABLET, FILM COATED | ORAL | ANDA205199 | Apotex Corp. | 60505-3483 | Amlodipine and Atorvastatin | AMLODIPINE BESYLATE; ATORVASTATIN CALCIUM TRIHYDRATE | HUMAN PRESCRIPTION DRUG |
| Amlodipine and Atorvastatin | 60505-3484-3 | 10 mg/1, 20 mg/1 | TABLET, FILM COATED | ORAL | ANDA205199 | Apotex Corp. | 60505-3484 | Amlodipine and Atorvastatin | AMLODIPINE BESYLATE; ATORVASTATIN CALCIUM TRIHYDRATE | HUMAN PRESCRIPTION DRUG |
| Amlodipine and Atorvastatin | 60505-3488-3 | 5 mg/1, 40 mg/1 | TABLET, FILM COATED | ORAL | ANDA205199 | Apotex Corp. | 60505-3488 | Amlodipine and Atorvastatin | AMLODIPINE BESYLATE; ATORVASTATIN CALCIUM TRIHYDRATE | HUMAN PRESCRIPTION DRUG |
| Amlodipine and Atorvastatin | 60505-3489-3 | 10 mg/1, 40 mg/1 | TABLET, FILM COATED | ORAL | ANDA205199 | Apotex Corp. | 60505-3489 | Amlodipine and Atorvastatin | AMLODIPINE BESYLATE; ATORVASTATIN CALCIUM TRIHYDRATE | HUMAN PRESCRIPTION DRUG |
| Amlodipine and Atorvastatin | 60505-3492-3 | 5 mg/1, 80 mg/1 | TABLET, FILM COATED | ORAL | ANDA205199 | Apotex Corp. | 60505-3492 | Amlodipine and Atorvastatin | AMLODIPINE BESYLATE; ATORVASTATIN CALCIUM TRIHYDRATE | HUMAN PRESCRIPTION DRUG |
| Amlodipine and Atorvastatin | 60505-3493-3 | 10 mg/1, 80 mg/1 | TABLET, FILM COATED | ORAL | ANDA205199 | Apotex Corp. | 60505-3493 | Amlodipine and Atorvastatin | AMLODIPINE BESYLATE; ATORVASTATIN CALCIUM TRIHYDRATE | HUMAN PRESCRIPTION DRUG |
| APO-VARENICLINE | 60505-4765-3 | .5 mg/1 | TABLET, FILM COATED | ORAL | | Apotex Corp | 60505-4765 | VARENICLINE | VARENICLINE TARTRATE | HUMAN PRESCRIPTION DRUG |
| APO-VARENICLINE | 60505-4766-8 | 1 mg/1 | TABLET, FILM COATED | ORAL | | Apotex Corp | 60505-4766 | VARENICLINE | VARENICLINE TARTRATE | HUMAN PRESCRIPTION DRUG |
| Aripiprazole | 60505-2675-8 | 15 mg/1 | TABLET | ORAL | ANDA078563 | Apotex Corp | 60505-2675 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG |
| Aripiprazole | 60505-2674-8 | 10 mg/1 | TABLET | ORAL | ANDA078563 | Apotex Corp | 60505-2674 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG |
| Aripiprazole | 60505-2677-3 | 30 mg/1 | TABLET | ORAL | ANDA078563 | Apotex Corp | 60505-2677 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG |
| Aripiprazole | 60505-2673-8 | 5 mg/1 | TABLET | ORAL | ANDA078563 | Apotex Corp | 60505-2673 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG |
| Aripiprazole | 60505-2677-8 | 30 mg/1 | TABLET | ORAL | ANDA078563 | Apotex Corp | 60505-2677 | Aripiprazole | ARIPIPRAZOLE | HUMAN PRESCRIPTION DRUG |

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| Proprietary Name | NDC Package Code | Strength | Dosage Form | Route | Appl. No. | Labeler Name | Product NDC | Nonproprietary Name | Substance Name | Prod Type |
|---|---|---|---|---|---|---|---|---|---|---|
| ATORVASTATIN CALCIUM | 60505-2671-6 | 80 mg/1 | TABLET, FILM COATED | ORAL | ANDA090548 | Apotex Corp. | 60505-2671 | ATORVASTATIN CALCIUM | ATORVASTATIN CALCIUM PROPYLENE GLYCOL SOLVATE | HUMAN PRESCRIPTION DRUG |
| ATORVASTATIN CALCIUM | 60505-2671-0 | 80 mg/1 | TABLET, FILM COATED | ORAL | ANDA090548 | Apotex Corp. | 60505-2671 | ATORVASTATIN CALCIUM | ATORVASTATIN CALCIUM PROPYLENE GLYCOL SOLVATE | HUMAN PRESCRIPTION DRUG |
| ATORVASTATIN CALCIUM | 60505-2671-5 | 80 mg/1 | TABLET, FILM COATED | ORAL | ANDA090548 | Apotex Corp. | 60505-2671 | ATORVASTATIN CALCIUM | ATORVASTATIN CALCIUM PROPYLENE GLYCOL SOLVATE | HUMAN PRESCRIPTION DRUG |
| ATORVASTATIN CALCIUM | 60505-2580-8 | 40 mg/1 | TABLET, FILM COATED | ORAL | ANDA090548 | Apotex Corp. | 60505-2580 | ATORVASTATIN CALCIUM | ATORVASTATIN CALCIUM PROPYLENE GLYCOL SOLVATE | HUMAN PRESCRIPTION DRUG |
| ATORVASTATIN CALCIUM | 60505-2579-7 | 20 mg/1 | TABLET, FILM COATED | ORAL | ANDA090548 | Apotex Corp. | 60505-2579 | ATORVASTATIN CALCIUM | ATORVASTATIN CALCIUM PROPYLENE GLYCOL SOLVATE | HUMAN PRESCRIPTION DRUG |
| ATORVASTATIN CALCIUM | 60505-2579-9 | 20 mg/1 | TABLET, FILM COATED | ORAL | ANDA090548 | Apotex Corp. | 60505-2579 | ATORVASTATIN CALCIUM | ATORVASTATIN CALCIUM PROPYLENE GLYCOL SOLVATE | HUMAN PRESCRIPTION DRUG |
| ATORVASTATIN CALCIUM | 60505-2580-4 | 40 mg/1 | TABLET, FILM COATED | ORAL | ANDA090548 | Apotex Corp. | 60505-2580 | ATORVASTATIN CALCIUM | ATORVASTATIN CALCIUM PROPYLENE GLYCOL SOLVATE | HUMAN PRESCRIPTION DRUG |
| ATORVASTATIN CALCIUM | 60505-2578-8 | 10 mg/1 | TABLET, FILM COATED | ORAL | ANDA090548 | Apotex Corp. | 60505-2578 | ATORVASTATIN CALCIUM | ATORVASTATIN CALCIUM PROPYLENE GLYCOL SOLVATE | HUMAN PRESCRIPTION DRUG |
| Atropine | 60505-6226-2 | 10 mg/mL | SOLUTION/ DROPS | OPHTHALMIC | ANDA213624 | Apotex Corp. | 60505-6226 | Atropine Sulfate | ATROPINE SULFATE | HUMAN PRESCRIPTION DRUG |
| Atropine | 60505-6226-8 | 10 mg/mL | SOLUTION/ DROPS | OPHTHALMIC | ANDA213624 | Apotex Corp. | 60505-6226 | Atropine Sulfate | ATROPINE SULFATE | HUMAN PRESCRIPTION DRUG |
| Atropine | 60505-6226-1 | 10 mg/mL | SOLUTION/ DROPS | OPHTHALMIC | ANDA213624 | Apotex Corp. | 60505-6226 | Atropine Sulfate | ATROPINE SULFATE | HUMAN PRESCRIPTION DRUG |
| Azelastine Hydrochloride | 60505-0923-8 | 137 ug/1 | SPRAY, METERED | NASAL | ANDA077954 | Apotex Corp. | 60505-0923 | azelastine hydrochloride | AZELASTINE HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |

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| Proprietary Name | NDC Package Code | Strength | Dosage Form | Route | Appl. No. | Labeler Name | Product NDC | Nonproprietary Name | Substance Name | Prod Type |
|---|---|---|---|---|---|---|---|---|---|---|
| AZELASTINE HYDROCHLORIDE | 60505-0578-8 | .5 mg/mL | SOLUTION/ DROPS | INTRAOCULAR | ANDA078621 | Apotex Corp. | 60505-0578 | AZELASTINE HYDROCHLORIDE | AZELASTINE HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| Azelastine Hydrochloride | 60505-0846-6 | 205.5 ug/1 | SPRAY, METERED | NASAL | ANDA201846 | Apotex Corp. | 60505-0846 | Azelastine Hydrochloride | AZELASTINE HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| Azelastine Hydrochloride and Fluticasone propionate | 60505-0953-3 | 137 ug/1, 50 ug/1 | SPRAY, METERED | NASAL | ANDA207712 | Apotex Corp. | 60505-0953 | Azelastine Hydrochloride and Fluticasone propionate | AZELASTINE HYDROCHLORIDE; FLUTICASONE PROPIONATE | HUMAN PRESCRIPTION DRUG |
| Balsalazide Disodium | 60505-2575-4 | 750 mg/1 | CAPSULE | ORAL | ANDA077883 | Apotex Corp. | 60505-2575 | Balsalazide Disodium | BALSALAZIDE DISODIUM | HUMAN PRESCRIPTION DRUG |
| Balsalazide Disodium | 60505-2575-3 | 750 mg/1 | CAPSULE | ORAL | ANDA077883 | Apotex Corp. | 60505-2575 | Balsalazide Disodium | BALSALAZIDE DISODIUM | HUMAN PRESCRIPTION DRUG |
| Balsalazide Disodium | 60505-2575-0 | 750 mg/1 | CAPSULE | ORAL | ANDA077883 | Apotex Corp. | 60505-2575 | Balsalazide Disodium | BALSALAZIDE DISODIUM | HUMAN PRESCRIPTION DRUG |
| Balsalazide Disodium | 60505-2575-7 | 750 mg/1 | CAPSULE | ORAL | ANDA077883 | Apotex Corp. | 60505-2575 | Balsalazide Disodium | BALSALAZIDE DISODIUM | HUMAN PRESCRIPTION DRUG |
| Bepotastine Besilate | 60505-6111-1 | 15 mg/mL | SOLUTION/ DROPS | OPHTHALMIC | ANDA206066 | Apotex Corp. | 60505-6111 | Bepotastine Besilate | BEPOTASTINE BESYLATE | HUMAN PRESCRIPTION DRUG |
| Bepotastine Besilate | 60505-6111-2 | 15 mg/mL | SOLUTION/ DROPS | OPHTHALMIC | ANDA206066 | Apotex Corp. | 60505-6111 | Bepotastine Besilate | BEPOTASTINE BESYLATE | HUMAN PRESCRIPTION DRUG |
| Bimatoprost | 60505-0583-4 | .3 mg/mL | SOLUTION/ DROPS | OPHTHALMIC | ANDA090449 | Apotex Corp. | 60505-0583 | Bimatoprost | BIMATOPROST | HUMAN PRESCRIPTION DRUG |
| Bimatoprost | 60505-0583-1 | .3 mg/mL | SOLUTION/ DROPS | OPHTHALMIC | ANDA090449 | Apotex Corp. | 60505-0583 | Bimatoprost | BIMATOPROST | HUMAN PRESCRIPTION DRUG |

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| Proprietary Name | NDC Package Code | Strength | Dosage Form | Route | Appl. No. | Labeler Name | Product NDC | Nonproprietary Name | Substance Name | Prod Type |
|---|---|---|---|---|---|---|---|---|---|---|
| Buprenorphine and Naloxone | 60505-7054-4 | 17 mg/1, 3 mg/1 | FILM | BUCCAL; SUBLINGUAL | ANDA217756 | Apotex Corp. | 60505-7054 | buprenorphine and naloxone | BUPRENORPHINE HYDROCHLORIDE; NALOXONE HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| Bupropion Hydrochloride | 60505-0130-9 | 75 mg/1 | TABLET, FILM COATED | ORAL | ANDA076143 | Apotex Corp. | 60505-0130 | Bupropion Hydrochloride | BUPROPION HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| Bupropion Hydrochloride | 60505-0137-9 | 100 mg/1 | TABLET, FILM COATED | ORAL | ANDA076143 | Apotex Corp. | 60505-0137 | Bupropion Hydrochloride | BUPROPION HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| Bupropion Hydrochloride | 60505-0157-7 | 150 mg/1 | TABLET, FILM COATED | ORAL | ANDA076143 | Apotex Corp. | 60505-0157 | Bupropion Hydrochloride | BUPROPION HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| Bupropion Hydrochloride | 60505-0158-1 | 75 mg/1 | TABLET, FILM COATED | ORAL | ANDA076143 | Apotex Corp. | 60505-0158 | Bupropion Hydrochloride | BUPROPION HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| Bupropion Hydrochloride | 60505-0158-3 | 75 mg/1 | TABLET, FILM COATED | ORAL | ANDA076143 | Apotex Corp. | 60505-0158 | Bupropion Hydrochloride | BUPROPION HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| Bupropion Hydrochloride | 60505-0158-6 | 75 mg/1 | TABLET, FILM COATED | ORAL | ANDA076143 | Apotex Corp. | 60505-0158 | Bupropion Hydrochloride | BUPROPION HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| Bupropion Hydrochloride | 60505-0157-1 | 100 mg/1 | TABLET, FILM COATED | ORAL | ANDA076143 | Apotex Corp. | 60505-0157 | Bupropion Hydrochloride | BUPROPION HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| Bupropion Hydrochloride | 60505-0158-7 | 75 mg/1 | TABLET, FILM COATED | ORAL | ANDA076143 | Apotex Corp. | 60505-0158 | Bupropion Hydrochloride | BUPROPION HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| Bupropion Hydrochloride | 60505-0157-3 | 100 mg/1 | TABLET, FILM COATED | ORAL | ANDA076143 | Apotex Corp. | 60505-0157 | Bupropion Hydrochloride | BUPROPION HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| Bupropion Hydrochloride | 60505-0157-6 | 100 mg/1 | TABLET, FILM COATED | ORAL | ANDA076143 | Apotex Corp. | 60505-0157 | Bupropion Hydrochloride | BUPROPION HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| Butorphanol Tartrate | 60505-0813-1 | 10 mg/mL | SPRAY | NASAL | ANDA075499 | Apotex Corp. | 60505-0813 | Butorphanol Tartrate | BUTORPHANOL TARTRATE | HUMAN PRESCRIPTION DRUG |
| Calcitonin Salmon | 60505-0823-0 | 200 [IU]/1 | SPRAY, METERED | NASAL | ANDA076396 | Apotex Corp. | 60505-0823 | Calcitonin Salmon | CALCITONIN SALMON | HUMAN PRESCRIPTION DRUG |

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| Proprietary Name | NDC Package Code | Strength | Dosage Form | Route | Appl. No. | Labeler Name | Product NDC | Nonproprietary Name | Substance Name | Prod Type |
|---|---|---|---|---|---|---|---|---|---|---|
| Calcitonin Salmon | 60505-0823-0 | 200 [IU]/1 | SPRAY, METERED | NASAL | ANDA076396 | Apotex Corp. | 60505-0823 | Calcitonin Salmon | CALCITONIN SALMON | HUMAN PRESCRIPTION DRUG |
| Carbamazepine | 60505-2906-0 | 200 mg/1 | CAPSULE, EXTENDED RELEASE | ORAL | ANDA078986 | Apotex Corp. | 60505-2906 | Carbamazepine | CARBAMAZEPINE | HUMAN PRESCRIPTION DRUG |
| Carbamazepine | 60505-2905-7 | 100 mg/1 | CAPSULE, EXTENDED RELEASE | ORAL | ANDA078986 | Apotex Corp. | 60505-2905 | Carbamazepine | CARBAMAZEPINE | HUMAN PRESCRIPTION DRUG |
| Carbamazepine | 60505-2904-3 | 200 mg/1 | CAPSULE, EXTENDED RELEASE | ORAL | ANDA078984 | Apotex Corp. | 60505-2904 | Carbamazepine | CARBAMAZEPINE | HUMAN PRESCRIPTION DRUG |
| CARBAMAZEPINE | 60505-0183-1 | 200 mg/1 | TABLET | ORAL | ANDA075941 | Apotex Corp. | 60505-0183 | CARBAMAZEPINE | CARBAMAZEPINE | HUMAN PRESCRIPTION DRUG |
| Carbamazepine | 60505-2903-0 | 100 mg/1 | CAPSULE, EXTENDED RELEASE | ORAL | ANDA078984 | Apotex Corp. | 60505-2903 | Carbamazepine | CARBAMAZEPINE | HUMAN PRESCRIPTION DRUG |
| Carbamazepine | 60505-2907-7 | 300 mg/1 | CAPSULE, EXTENDED RELEASE | ORAL | ANDA078986 | Apotex Corp. | 60505-2907 | Carbamazepine | CARBAMAZEPINE | HUMAN PRESCRIPTION DRUG |
| Carbamazepine | 60505-2905-3 | 100 mg/1 | CAPSULE, EXTENDED RELEASE | ORAL | ANDA078986 | Apotex Corp. | 60505-2905 | Carbamazepine | CARBAMAZEPINE | HUMAN PRESCRIPTION DRUG |
| Carbamazepine | 60505-2906-7 | 200 mg/1 | CAPSULE, EXTENDED RELEASE | ORAL | ANDA078986 | Apotex Corp. | 60505-2906 | Carbamazepine | CARBAMAZEPINE | HUMAN PRESCRIPTION DRUG |
| Carbamazepine | 60505-2907-3 | 300 mg/1 | CAPSULE, EXTENDED RELEASE | ORAL | ANDA078986 | Apotex Corp. | 60505-2907 | Carbamazepine | CARBAMAZEPINE | HUMAN PRESCRIPTION DRUG |
| Carbamazepine | 60505-2907-9 | 300 mg/1 | CAPSULE, EXTENDED RELEASE | ORAL | ANDA078986 | Apotex Corp. | 60505-2907 | Carbamazepine | CARBAMAZEPINE | HUMAN PRESCRIPTION DRUG |
| CARBAMAZEPINE | 60505-0183-0 | 200 mg/1 | TABLET | ORAL | ANDA075948 | Apotex Corp. | 60505-0183 | CARBAMAZEPINE | CARBAMAZEPINE | HUMAN PRESCRIPTION DRUG |
| Carvedilol Phosphate | 60505-3478-1 | 10 mg/1 | CAPSULE, EXTENDED RELEASE | ORAL | NDA022012 | Apotex Corp. | 60505-3478 | carvedilol phosphate | CARVEDILOL PHOSPHATE | HUMAN PRESCRIPTION DRUG |

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|---|---|---|---|---|---|---|---|---|---|---|
| Cefepime | 60505-6147-4 | 2 g/1 | INJECTION, POWDER, FOR SOLUTION | INTRAVENOUS | ANDA202754 | Apotex Corp. | 60505-6147 | Cefepime | CEFEPIME HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| Ceftriaxone Sodium | 60505-6151-4 | 250 mg/1 | INJECTION, POWDER, FOR SOLUTION | INTRAMUSCULAR; INTRAVENOUS | ANDA202702 | Apotex Corp. | 60505-6151 | Ceftriaxone Sodium | CEFTRIAXONE SODIUM | HUMAN PRESCRIPTION DRUG |
| Ceftriaxone Sodium | 60505-6152-1 | 500 mg/1 | INJECTION, POWDER, FOR SOLUTION | INTRAMUSCULAR; INTRAVENOUS | ANDA202702 | Apotex Corp. | 60505-6152 | Ceftriaxone Sodium | CEFTRIAXONE SODIUM | HUMAN PRESCRIPTION DRUG |
| Ceftriaxone Sodium | 60505-6153-4 | 500 mg/1 | INJECTION, POWDER, FOR SOLUTION | INTRAMUSCULAR; INTRAVENOUS | ANDA202702 | Apotex Corp. | 60505-6153 | Ceftriaxone Sodium | CEFTRIAXONE SODIUM | HUMAN PRESCRIPTION DRUG |
| Ceftriaxone Sodium | 60505-6148-0 | 1 g/1 | INJECTION, POWDER, FOR SOLUTION | INTRAMUSCULAR; INTRAVENOUS | ANDA202702 | Apotex Corp. | 60505-6148 | Ceftriaxone Sodium | CEFTRIAXONE SODIUM | HUMAN PRESCRIPTION DRUG |
| Ceftriaxone Sodium | 60505-6148-4 | 1 g/1 | INJECTION, POWDER, FOR SOLUTION | INTRAMUSCULAR; INTRAVENOUS | ANDA202702 | Apotex Corp. | 60505-6148 | Ceftriaxone Sodium | CEFTRIAXONE SODIUM | HUMAN PRESCRIPTION DRUG |
| Ceftriaxone Sodium | 60505-6151-1 | 250 mg/1 | INJECTION, POWDER, FOR SOLUTION | INTRAMUSCULAR; INTRAVENOUS | ANDA202702 | Apotex Corp. | 60505-6151 | Ceftriaxone Sodium | CEFTRIAXONE SODIUM | HUMAN PRESCRIPTION DRUG |

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|---|---|---|---|---|---|---|---|---|---|---|
| Ceftriaxone Sodium | 60505-6149-4 | 2 g/1 | INJECTION, POWDER, FOR SOLUTION | INTRAMUSCULAR; INTRAVENOUS | ANDA202702 | Apotex Corp. | 60505-6149 | Ceftriaxone Sodium | CEFTRIAXONE SODIUM | HUMAN PRESCRIPTION DRUG |
| Ceftriaxone Sodium | 60505-6150-8 | 10 g/1 | INJECTION, POWDER, FOR SOLUTION | INTRAVENOUS | ANDA209218 | Apotex Corp. | 60505-6150 | Ceftriaxone Sodium | CEFTRIAXONE SODIUM | HUMAN PRESCRIPTION DRUG |
| Celecoxib | 60505-3849-0 | 200 mg/1 | CAPSULE | ORAL | ANDA204197 | Apotex Corp. | 60505-3849 | Celecoxib | CELECOXIB | HUMAN PRESCRIPTION DRUG |
| Celecoxib | 60505-3848-6 | 100 mg/1 | CAPSULE | ORAL | ANDA204197 | Apotex Corp. | 60505-3848 | Celecoxib | CELECOXIB | HUMAN PRESCRIPTION DRUG |
| Celecoxib | 60505-3849-2 | 200 mg/1 | CAPSULE | ORAL | ANDA204197 | Apotex Corp. | 60505-3849 | Celecoxib | CELECOXIB | HUMAN PRESCRIPTION DRUG |
| Celecoxib | 60505-3849-1 | 200 mg/1 | CAPSULE | ORAL | ANDA204197 | Apotex Corp. | 60505-3849 | Celecoxib | CELECOXIB | HUMAN PRESCRIPTION DRUG |
| Celecoxib | 60505-3847-8 | 50 mg/1 | CAPSULE | ORAL | ANDA204197 | Apotex Corp. | 60505-3847 | Celecoxib | CELECOXIB | HUMAN PRESCRIPTION DRUG |
| Celecoxib | 60505-3847-1 | 50 mg/1 | CAPSULE | ORAL | ANDA204197 | Apotex Corp. | 60505-3847 | Celecoxib | CELECOXIB | HUMAN PRESCRIPTION DRUG |
| Celecoxib | 60505-3847-6 | 50 mg/1 | CAPSULE | ORAL | ANDA204197 | Apotex Corp. | 60505-3847 | Celecoxib | CELECOXIB | HUMAN PRESCRIPTION DRUG |
| Celecoxib | 60505-3848-3 | 100 mg/1 | CAPSULE | ORAL | ANDA204197 | Apotex Corp. | 60505-3848 | Celecoxib | CELECOXIB | HUMAN PRESCRIPTION DRUG |
| Celecoxib | 60505-3847-3 | 50 mg/1 | CAPSULE | ORAL | ANDA204197 | Apotex Corp. | 60505-3847 | Celecoxib | CELECOXIB | HUMAN PRESCRIPTION DRUG |
| Celecoxib | 60505-3848-1 | 100 mg/1 | CAPSULE | ORAL | ANDA204197 | Apotex Corp. | 60505-3848 | Celecoxib | CELECOXIB | HUMAN PRESCRIPTION DRUG |
| Celecoxib | 60505-3848-8 | 100 mg/1 | CAPSULE | ORAL | ANDA204197 | Apotex Corp. | 60505-3848 | Celecoxib | CELECOXIB | HUMAN PRESCRIPTION DRUG |
| Celecoxib | 60505-3849-8 | 200 mg/1 | CAPSULE | ORAL | ANDA204197 | Apotex Corp. | 60505-3849 | Celecoxib | CELECOXIB | HUMAN PRESCRIPTION DRUG |
| cilostazol | 60505-2521-1 | 50 mg/1 | TABLET | ORAL | ANDA077933 | Apotex Corp. | 60505-2521 | cilostazol | CILOSTAZOL | HUMAN PRESCRIPTION DRUG |

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|---|---|---|---|---|---|---|---|---|---|---|
| + Deferoxamine mesylate | 60505-6236-4 | 500 mg/1 | INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAMUSCULAR; INTRAVENOUS; SUBCUTANEOUS | ANDA207384 | Apotex Corp. | 60505-6236 | Deferoxamine mesylate | DEFEROXAMINE MESYLATE | HUMAN PRESCRIPTION DRUG |
| + Deferoxamine mesylate | 60505-6237-1 | 2 g/1 | INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAMUSCULAR; INTRAVENOUS | ANDA207384 | Apotex Corp. | 60505-6237 | Deferoxamine mesylate | DEFEROXAMINE MESYLATE | HUMAN PRESCRIPTION DRUG |
| + Desmopressin Acetate | 60505-0257-1 | .1 mg/1 | TABLET | ORAL | ANDA077414 | Apotex Corp. | 60505-0257 | desmopressin acetate | DESMOPRESSIN ACETATE | HUMAN PRESCRIPTION DRUG |
| + Desmopressin Acetate | 60505-0258-1 | .2 mg/1 | TABLET | ORAL | ANDA077414 | Apotex Corp. | 60505-0258 | desmopressin acetate | DESMOPRESSIN ACETATE | HUMAN PRESCRIPTION DRUG |
| + DESMOPRESSIN ACETATE | 60505-0816-0 | 10 ug/1 | SPRAY | NASAL | ANDA076783 | Apotex Corp. | 60505-0816 | DESMOPRESSIN ACETATE | DESMOPRESSIN ACETATE | HUMAN PRESCRIPTION DRUG |
| + Diclofenac Sodium | 60505-0406-3 | 20 mg/g | SOLUTION | TOPICAL | ANDA207716 | Apotex Corp. | 60505-0406 | Diclofenac Sodium | DICLOFENAC SODIUM | HUMAN PRESCRIPTION DRUG |
| + Diclofenac Sodium | 60505-0299-5 | 10.05 mg/mL | SOLUTION | TOPICAL | ANDA202027 | Apotex Corp. | 60505-0299 | Diclofenac Sodium | DICLOFENAC SODIUM | HUMAN PRESCRIPTION DRUG |
| + DILTIAZEM HYDROCHLORIDE | 60505-0815-6 | 180 mg/1 | CAPSULE, EXTENDED RELEASE | ORAL | ANDA074943 | Apotex Corp. | 60505-0815 | DILTIAZEM HYDROCHLORIDE | DILTIAZEM HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| + DILTIAZEM HYDROCHLORIDE | 60505-0816-6 | 240 mg/1 | CAPSULE, EXTENDED RELEASE | ORAL | ANDA074943 | Apotex Corp. | 60505-0816 | DILTIAZEM HYDROCHLORIDE | DILTIAZEM HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| + DILTIAZEM HYDROCHLORIDE | 60505-0813-6 | 120 mg/1 | CAPSULE, EXTENDED RELEASE | ORAL | ANDA074943 | Apotex Corp. | 60505-0813 | DILTIAZEM HYDROCHLORIDE | DILTIAZEM HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| + DILTIAZEM HYDROCHLORIDE | 60505-0814-6 | 240 mg/1 | CAPSULE, EXTENDED RELEASE | ORAL | ANDA074943 | Apotex Corp. | 60505-0814 | DILTIAZEM HYDROCHLORIDE | DILTIAZEM HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| + DILTIAZEM HYDROCHLORIDE | 60505-0814-5 | 120 mg/1 | CAPSULE, EXTENDED RELEASE | ORAL | ANDA074943 | Apotex Corp. | 60505-0814 | DILTIAZEM HYDROCHLORIDE | DILTIAZEM HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |

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|---|---|---|---|---|---|---|---|---|---|---|
| + Doxazosin | 60505-0094-1 | 2 mg/1 | TABLET | ORAL | ANDA075680 | Apotex Corp. | 60505-0094 | Doxazosin | DOXAZOSIN MESYLATE | HUMAN PRESCRIPTION DRUG |
| + Doxazosin | 60505-0095-8 | 8 mg/1 | TABLET | ORAL | ANDA075680 | Apotex Corp. | 60505-0095 | Doxazosin | DOXAZOSIN MESYLATE | HUMAN PRESCRIPTION DRUG |
| + Doxazosin | 60505-0093-0 | 1 mg/1 | TABLET | ORAL | ANDA075680 | Apotex Corp. | 60505-0093 | Doxazosin | DOXAZOSIN MESYLATE | HUMAN PRESCRIPTION DRUG |
| + Doxazosin | 60505-0096-1 | 8 mg/1 | TABLET | ORAL | ANDA075680 | Apotex Corp. | 60505-0096 | Doxazosin | DOXAZOSIN MESYLATE | HUMAN PRESCRIPTION DRUG |
| + Doxazosin | 60505-0093-1 | 1 mg/1 | TABLET | ORAL | ANDA075680 | Apotex Corp. | 60505-0093 | Doxazosin | DOXAZOSIN MESYLATE | HUMAN PRESCRIPTION DRUG |
| + Doxazosin | 60505-0095-0 | 4 mg/1 | TABLET | ORAL | ANDA075680 | Apotex Corp. | 60505-0095 | Doxazosin | DOXAZOSIN MESYLATE | HUMAN PRESCRIPTION DRUG |
| + Doxazosin | 60505-0096-0 | 8 mg/1 | TABLET | ORAL | ANDA075680 | Apotex Corp. | 60505-0096 | Doxazosin | DOXAZOSIN MESYLATE | HUMAN PRESCRIPTION DRUG |
| + Doxazosin | 60505-0094-0 | 2 mg/1 | TABLET | ORAL | ANDA075680 | Apotex Corp. | 60505-0094 | Doxazosin | DOXAZOSIN MESYLATE | HUMAN PRESCRIPTION DRUG |
| + Doxazosin | 60505-0095-1 | 4 mg/1 | TABLET | ORAL | ANDA075680 | Apotex Corp. | 60505-0095 | Doxazosin | DOXAZOSIN MESYLATE | HUMAN PRESCRIPTION DRUG |
| + Doxycycline Hyclate | 60505-4382-6 | 75 mg/1 | TABLET, COATED | ORAL | ANDA209243 | Apotex Corp. | 60505-4382 | Doxycycline Hyclate | DOXYCYCLINE HYCLATE | HUMAN PRESCRIPTION DRUG |
| + Doxycycline Hyclate | 60505-4384-6 | 150 mg/1 | TABLET, COATED | ORAL | ANDA209243 | Apotex Corp. | 60505-4384 | Doxycycline Hyclate | DOXYCYCLINE HYCLATE | HUMAN PRESCRIPTION DRUG |
| + Duloxetine Hydrochloride | 60505-2993-2 | 60 mg/1 | CAPSULE, DELAYED RELEASE | ORAL | ANDA202043 | Apotex Corp. | 60505-2993 | Duloxetine Hydrochloride | DULOXETINE HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| + Duloxetine Hydrochloride | 60505-2995-6 | 20 mg/1 | CAPSULE, DELAYED RELEASE | ORAL | ANDA202043 | Apotex Corp. | 60505-2995 | Duloxetine Hydrochloride | DULOXETINE HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| + Duloxetine Hydrochloride | 60505-2994-2 | 30 mg/1 | CAPSULE, DELAYED RELEASE | ORAL | ANDA202043 | Apotex Corp. | 60505-2994 | Duloxetine Hydrochloride | DULOXETINE HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| + Emtricitabine and Tenofovir Disoproxil Fumarate | 60505-4202-3 | 200 mg/1; 300 mg/1 | TABLET, FILM COATED | ORAL | ANDA202142 | Apotex Corp. | 60505-4202 | emtricitabine and tenofovir disoproxil fumarate | EMTRICITABINE; TENOFOVIR DISOPROXIL FUMARATE | HUMAN PRESCRIPTION DRUG |
| + Enoxaparin Sodium | 60505-0791-0 | 80 mg/.8mL | INJECTION | SUBCUTANEOUS | ANDA078990 | Apotex Corp. | 60505-0791 | enoxaparin sodium | ENOXAPARIN SODIUM | HUMAN PRESCRIPTION DRUG |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Fenofibrate | 68325-3121-1 | 130 mg/1 | CAPSULE | ORAL | ANDA202252 | Aprotex Corp. | 68325-3121 | Fenofibrate | FENOFIBRATE | | | HUMAN PRESCRIPTION DRUG |
| FENTANYL | 68325-7062-2 | 50 ug/h | PATCH, EXTENDED RELEASE | TRANSDERMAL | ANDA077449 | Aprotex Corp. | 68325-7062 | FENTANYL | FENTANYL | | | HUMAN PRESCRIPTION DRUG |
| FENTANYL | 68325-7067-2 | 87.5 ug/h | PATCH, EXTENDED RELEASE | TRANSDERMAL | ANDA077449 | Aprotex Corp. | 68325-7067 | FENTANYL | FENTANYL | | | HUMAN PRESCRIPTION DRUG |
| FENTANYL | 68325-7008-2 | 75 ug/h | PATCH, EXTENDED RELEASE | TRANSDERMAL | ANDA077449 | Aprotex Corp. | 68325-7008 | FENTANYL | FENTANYL | | | HUMAN PRESCRIPTION DRUG |
| FENTANYL | 68325-7009-2 | 100 ug/h | PATCH, EXTENDED RELEASE | TRANSDERMAL | ANDA077449 | Aprotex Corp. | 68325-7009 | FENTANYL | FENTANYL | | | HUMAN PRESCRIPTION DRUG |
| FENTANYL | 68325-7011-2 | 25 ug/h | PATCH, EXTENDED RELEASE | TRANSDERMAL | ANDA077449 | Aprotex Corp. | 68325-7011 | FENTANYL | FENTANYL | | | HUMAN PRESCRIPTION DRUG |
| FENTANYL | 68325-7013-2 | 75 ug/h | PATCH, EXTENDED RELEASE | TRANSDERMAL | ANDA077449 | Aprotex Corp. | 68325-7013 | FENTANYL | FENTANYL | | | HUMAN PRESCRIPTION DRUG |
| FENTANYL | 68325-7015-2 | 37.5 ug/h | PATCH, EXTENDED RELEASE | TRANSDERMAL | ANDA077449 | Aprotex Corp. | 68325-7015 | FENTANYL | FENTANYL | | | HUMAN PRESCRIPTION DRUG |
| FENTANYL | 68325-7016-2 | 62.5 ug/h | PATCH, EXTENDED RELEASE | TRANSDERMAL | ANDA077449 | Aprotex Corp. | 68325-7016 | FENTANYL | FENTANYL | | | HUMAN PRESCRIPTION DRUG |
| FENTANYL | 68325-7017-2 | 87.5 ug/h | PATCH, EXTENDED RELEASE | TRANSDERMAL | ANDA077449 | Aprotex Corp. | 68325-7017 | FENTANYL | FENTANYL | | | HUMAN PRESCRIPTION DRUG |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|
| FENTANYL | 68325-7014-2 | 100 ug/h | PATCH, EXTENDED RELEASE | TRANSDERMAL | ANDA077449 | Aprotex Corp. | 68325-7014 | FENTANYL | FENTANYL | | | HUMAN PRESCRIPTION DRUG |
| FENTANYL | 68325-7063-2 | 25 ug/h | PATCH, EXTENDED RELEASE | TRANSDERMAL | ANDA077449 | Aprotex Corp. | 68325-7063 | FENTANYL | FENTANYL | | | HUMAN PRESCRIPTION DRUG |
| FENTANYL | 68325-7066-2 | 62.5 ug/h | PATCH, EXTENDED RELEASE | TRANSDERMAL | ANDA077449 | Aprotex Corp. | 68325-7066 | FENTANYL | FENTANYL | | | HUMAN PRESCRIPTION DRUG |
| FENTANYL | 68325-7010-2 | 12 ug/h | PATCH, EXTENDED RELEASE | TRANSDERMAL | ANDA077449 | Aprotex Corp. | 68325-7010 | FENTANYL | FENTANYL | | | HUMAN PRESCRIPTION DRUG |
| FENTANYL | 68325-7001-2 | 25 ug/h | PATCH, EXTENDED RELEASE | TRANSDERMAL | ANDA077449 | Aprotex Corp. | 68325-7001 | FENTANYL | FENTANYL | | | HUMAN PRESCRIPTION DRUG |
| FENTANYL | 68325-7004-2 | 100 ug/h | PATCH, EXTENDED RELEASE | TRANSDERMAL | ANDA077449 | Aprotex Corp. | 68325-7004 | FENTANYL | FENTANYL | | | HUMAN PRESCRIPTION DRUG |
| FENTANYL | 68325-7006-2 | 25 ug/h | PATCH, EXTENDED RELEASE | TRANSDERMAL | ANDA077449 | Aprotex Corp. | 68325-7006 | FENTANYL | FENTANYL | | | HUMAN PRESCRIPTION DRUG |
| FENTANYL | 68325-7007-2 | 50 ug/h | PATCH, EXTENDED RELEASE | TRANSDERMAL | ANDA077449 | Aprotex Corp. | 68325-7007 | FENTANYL | FENTANYL | | | HUMAN PRESCRIPTION DRUG |
| FENTANYL | 68325-7012-2 | 50 ug/h | PATCH, EXTENDED RELEASE | TRANSDERMAL | ANDA077449 | Aprotex Corp. | 68325-7012 | FENTANYL | FENTANYL | | | HUMAN PRESCRIPTION DRUG |

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| Quinidine extended-release | 60505-3929-1 | 2 mg/1 | TABLET, EXTENDED RELEASE | ORAL | ANDA205432 | Apotex Corp. | 60505-3929 | quinidine | QUINIDINE HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| Quinidine extended-release | 60505-3930-1 | 4 mg/1 | TABLET, EXTENDED RELEASE | ORAL | ANDA205432 | Apotex Corp. | 60505-3930 | quinidine | QUINIDINE HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| IBANDRONATE SODIUM | 60505-2715-0 | 150 mg/1 | TABLET, FILM COATED | ORAL | ANDA078948 | Apotex Corp | 60505-2715 | IBANDRONATE SODIUM | IBANDRONATE SODIUM | HUMAN PRESCRIPTION DRUG |
| Ibandronate Sodium | 60505-6097-0 | 3 mg/3mL | INJECTION | INTRAVENOUS | ANDA204222 | Apotex Corp. | 60505-6097 | ibandronate sodium | IBANDRONATE SODIUM | HUMAN PRESCRIPTION DRUG |
| ICATIBANT | 60505-6214-1 | 30 mg/3ml | INJECTION, SOLUTION | SUBCUTANEOUS | ANDA212981 | Apotex Corp. | 60505-6214 | icatibant acetate | ICATIBANT ACETATE | HUMAN PRESCRIPTION DRUG |
| Icosapent Ethyl | 60505-4033-1 | 1 g/1 | CAPSULE | ORAL | ANDA209427 | Apotex Corp | 60505-4033 | Icosapent Ethyl | ICOSAPENT ETHYL | HUMAN PRESCRIPTION DRUG |
| Imatinib Mesylate | 60505-2908-1 | 100 mg/1 | TABLET, FILM COATED | ORAL | ANDA079179 | Apotex Corp | 60505-2908 | Imatinib Mesylate | IMATINIB MESYLATE | HUMAN PRESCRIPTION DRUG |
| Imatinib Mesylate | 60505-2901-1 | 400 mg/1 | TABLET, FILM COATED | ORAL | ANDA079179 | Apotex Corp | 60505-2901 | Imatinib Mesylate | IMATINIB MESYLATE | HUMAN PRESCRIPTION DRUG |
| Imatinib Mesylate | 60505-2901-0 | 400 mg/1 | TABLET, FILM COATED | ORAL | ANDA079179 | Apotex Corp | 60505-2901 | Imatinib Mesylate | IMATINIB MESYLATE | HUMAN PRESCRIPTION DRUG |
| Imatinib Mesylate | 60505-2900-1 | 100 mg/1 | TABLET, FILM COATED | ORAL | ANDA079179 | Apotex Corp | 60505-2900 | Imatinib Mesylate | IMATINIB MESYLATE | HUMAN PRESCRIPTION DRUG |
| Imatinib Mesylate | 60505-2900-0 | 100 mg/1 | TABLET, FILM COATED | ORAL | ANDA079179 | Apotex Corp | 60505-2900 | Imatinib Mesylate | IMATINIB MESYLATE | HUMAN PRESCRIPTION DRUG |
| Imatinib Mesylate | 60505-2907-1 | 400 mg/1 | TABLET, FILM COATED | ORAL | ANDA079179 | Apotex Corp | 60505-2907 | Imatinib Mesylate | IMATINIB MESYLATE | HUMAN PRESCRIPTION DRUG |
| Imatinib Mesylate | 60505-2900-3 | 100 mg/1 | TABLET, FILM COATED | ORAL | ANDA079179 | Apotex Corp | 60505-2900 | Imatinib Mesylate | IMATINIB MESYLATE | HUMAN PRESCRIPTION DRUG |

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|---|---|---|---|---|---|---|---|---|---|---|
| Imatinib Mesylate | 60505-2901-1 | 400 mg/1 | TABLET, FILM COATED | ORAL | ANDA079179 | Apotex Corp | 60505-2901 | Imatinib Mesylate | IMATINIB MESYLATE | HUMAN PRESCRIPTION DRUG |
| Imatinib Mesylate | 60505-2901-2 | 400 mg/1 | TABLET, FILM COATED | ORAL | ANDA079179 | Apotex Corp | 60505-2901 | Imatinib Mesylate | IMATINIB MESYLATE | HUMAN PRESCRIPTION DRUG |
| Imatinib Mesylate | 60505-2908-3 | 100 mg/1 | TABLET, FILM COATED | ORAL | ANDA079179 | Apotex Corp | 60505-2908 | Imatinib Mesylate | IMATINIB MESYLATE | HUMAN PRESCRIPTION DRUG |
| Ipratropium Bromide | 60505-0826-1 | 21 ug/1 | SPRAY, METERED | NASAL | ANDA076166 | Apotex Corp. | 60505-0826 | Ipratropium Bromide | IPRATROPIUM BROMIDE | HUMAN PRESCRIPTION DRUG |
| Ipratropium Bromide | 60505-0827-1 | 42 ug/1 | SPRAY, METERED | NASAL | ANDA076166 | Apotex Corp. | 60505-0827 | Ipratropium Bromide | IPRATROPIUM BROMIDE | HUMAN PRESCRIPTION DRUG |
| Irinotecan Hydrochloride | 60505-6128-1 | 20 mg/mL | INJECTION, SOLUTION | INTRAVENOUS | ANDA203380 | Apotex Corp. | 60505-6128 | Irinotecan Hydrochloride | IRINOTECAN HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| Irinotecan Hydrochloride | 60505-6128-0 | 20 mg/mL | INJECTION, SOLUTION | INTRAVENOUS | ANDA203380 | Apotex Corp | 60505-6128 | Irinotecan Hydrochloride | IRINOTECAN HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| Ketorolac Tromethamine | 60505-1003-1 | 5 mg/mL | SOLUTION/ DROPS | OPHTHALMIC | ANDA076109 | Apotex Corp. | 60505-1003 | ketorolac tromethamine | KETOROLAC TROMETHAMINE | HUMAN PRESCRIPTION DRUG |
| Ketorolac Tromethamine | 60505-1003-2 | 5 mg/mL | SOLUTION/ DROPS | OPHTHALMIC | ANDA076109 | Apotex Corp. | 60505-1003 | ketorolac tromethamine | KETOROLAC TROMETHAMINE | HUMAN PRESCRIPTION DRUG |
| LAMIVUDINE | 60505-3251-0 | 150 mg/1 | TABLET, FILM COATED | ORAL | ANDA091606 | Apotex Corp. | 60505-3251 | lamivudine | LAMIVUDINE | HUMAN PRESCRIPTION DRUG |
| LAMIVUDINE | 60505-3252-0 | 300 mg/1 | TABLET, FILM COATED | ORAL | ANDA091606 | Apotex Corp. | 60505-3252 | lamivudine | LAMIVUDINE | HUMAN PRESCRIPTION DRUG |
| Lamivudine | 60505-3259-0 | 100 mg/1 | TABLET, FILM COATED | ORAL | ANDA202941 | Apotex Corp | 60505-3259 | Lamivudine | LAMIVUDINE | HUMAN PRESCRIPTION DRUG |
| LAMIVUDINE | 60505-3253-0 | 300 mg/1 | TABLET, FILM COATED | ORAL | ANDA091606 | Apotex Corp. | 60505-3253 | lamivudine | LAMIVUDINE | HUMAN PRESCRIPTION DRUG |

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|---|---|---|---|---|---|---|---|---|---|---|
| Midodrine Hydrochloride | 66505-1321-1 | 5 mg/1 | TABLET | ORAL | ANDA077744 | Apotex Corp | 66505-1321 | Midodrine Hydrochloride | MIDODRINE HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| Midodrine Hydrochloride | 66505-1325-1 | 2.5 mg/1 | TABLET | ORAL | ANDA077744 | Apotex Corp | 66505-1325 | Midodrine Hydrochloride | MIDODRINE HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| Midodrine Hydrochloride | 66505-1325-3 | 10 mg/1 | TABLET | ORAL | ANDA077744 | Apotex Corp | 66505-1325 | Midodrine Hydrochloride | MIDODRINE HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| Midodrine Hydrochloride | 66505-1325-5 | 10 mg/1 | TABLET | ORAL | ANDA077744 | Apotex Corp | 66505-1325 | Midodrine Hydrochloride | MIDODRINE HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| Mirtazapine | 66505-0247-2 | 15 mg/1 | TABLET, FILM COATED | ORAL | ANDA077666 | Apotex Corp. | 66505-0247 | Mirtazapine | MIRTAZAPINE | HUMAN PRESCRIPTION DRUG |
| Mirtazapine | 66505-0248-1 | 30 mg/1 | TABLET, FILM COATED | ORAL | ANDA077666 | Apotex Corp. | 66505-0248 | Mirtazapine | MIRTAZAPINE | HUMAN PRESCRIPTION DRUG |
| Mirtazapine | 66505-0248-6 | 30 mg/1 | TABLET, FILM COATED | ORAL | ANDA077666 | Apotex Corp. | 66505-0248 | Mirtazapine | MIRTAZAPINE | HUMAN PRESCRIPTION DRUG |
| Mirtazapine | 66505-0249-1 | 45 mg/1 | TABLET, FILM COATED | ORAL | ANDA077666 | Apotex Corp. | 66505-0249 | Mirtazapine | MIRTAZAPINE | HUMAN PRESCRIPTION DRUG |
| Mirtazapine | 66505-0249-6 | 45 mg/1 | TABLET, FILM COATED | ORAL | ANDA077666 | Apotex Corp. | 66505-0249 | Mirtazapine | MIRTAZAPINE | HUMAN PRESCRIPTION DRUG |
| Mirtazapine | 66505-0249-9 | 45 mg/1 | TABLET, FILM COATED | ORAL | ANDA077666 | Apotex Corp. | 66505-0249 | Mirtazapine | MIRTAZAPINE | HUMAN PRESCRIPTION DRUG |
| Mirtazapine | 66505-0247-1 | 15 mg/1 | TABLET, FILM COATED | ORAL | ANDA077666 | Apotex Corp. | 66505-0247 | Mirtazapine | MIRTAZAPINE | HUMAN PRESCRIPTION DRUG |
| Mirtazapine | 66505-0247-3 | 15 mg/1 | TABLET, FILM COATED | ORAL | ANDA077666 | Apotex Corp. | 66505-0247 | Mirtazapine | MIRTAZAPINE | HUMAN PRESCRIPTION DRUG |
| Mirtazapine | 66505-0247-5 | 15 mg/1 | TABLET, FILM COATED | ORAL | ANDA077666 | Apotex Corp. | 66505-0247 | Mirtazapine | MIRTAZAPINE | HUMAN PRESCRIPTION DRUG |
| Mirtazapine | 66505-0248-6 | 30 mg/1 | TABLET, FILM COATED | ORAL | ANDA077666 | Apotex Corp. | 66505-0248 | Mirtazapine | MIRTAZAPINE | HUMAN PRESCRIPTION DRUG |
| Mirtazapine | 66505-0249-3 | 45 mg/1 | TABLET, FILM COATED | ORAL | ANDA077666 | Apotex Corp. | 66505-0249 | Mirtazapine | MIRTAZAPINE | HUMAN PRESCRIPTION DRUG |
| Mirtazapine | 66505-0248-3 | 30 mg/1 | TABLET, FILM COATED | ORAL | ANDA077666 | Apotex Corp. | 66505-0248 | Mirtazapine | MIRTAZAPINE | HUMAN PRESCRIPTION DRUG |

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|---|---|---|---|---|---|---|---|---|---|---|
| Modafinil | 66505-2526-7 | 100 mg/1 | TABLET | ORAL | ANDA077667 | Apotex Corp. | 66505-2526 | modafinil | MODAFINIL | HUMAN PRESCRIPTION DRUG |
| Modafinil | 66505-2526-1 | 100 mg/1 | TABLET | ORAL | ANDA077667 | Apotex Corp. | 66505-2526 | modafinil | MODAFINIL | HUMAN PRESCRIPTION DRUG |
| Modafinil | 66505-2527-1 | 200 mg/1 | TABLET | ORAL | ANDA077667 | Apotex Corp. | 66505-2527 | modafinil | MODAFINIL | HUMAN PRESCRIPTION DRUG |
| Modafinil | 66505-2527-3 | 200 mg/1 | TABLET | ORAL | ANDA077667 | Apotex Corp. | 66505-2527 | modafinil | MODAFINIL | HUMAN PRESCRIPTION DRUG |
| MOMETASONE FUROATE | 66505-0833-1 | 50 ug/1 | SPRAY, METERED | NASAL | ANDA091181 | Apotex Corp. | 66505-0830 | MOMETASONE FUROATE | MOMETASONE | HUMAN PRESCRIPTION DRUG |
| Moxifloxacin | 66505-0582-4 | 5 mg/mL | SOLUTION/ DROPS | OPHTHALMIC | ANDA090880 | Apotex Corp. | 66505-0582 | moxifloxacin | MOXIFLOXACIN HYDROCHLORIDE MONOHYDRATE | HUMAN PRESCRIPTION DRUG |
| Mycophenolic Acid | 66505-2965-7 | 180 mg/1 | TABLET, DELAYED RELEASE | ORAL | ANDA091552 | Apotex Corp | 66505-2965 | Mycophenolic Acid | MYCOPHENOLATE SODIUM | HUMAN PRESCRIPTION DRUG |
| Mycophenolic Acid | 66505-2966-7 | 360 mg/1 | TABLET, DELAYED RELEASE | ORAL | ANDA091552 | Apotex Corp | 66505-2966 | Mycophenolic Acid | MYCOPHENOLATE SODIUM | HUMAN PRESCRIPTION DRUG |
| Nicotine | 66505-7091-2 | 7 mg/24h | PATCH | TRANSDERMAL | ANDA074612 | Apotex Corp. | 66505-7091 | Nicotine | NICOTINE | HUMAN DRUG |
| Nicotine | 66505-7092-2 | 14 mg/24h | PATCH | TRANSDERMAL | ANDA074612 | Apotex Corp. | 66505-7092 | Nicotine | NICOTINE | HUMAN DRUG |
| Nicotine | 66505-7093-2 | 21 mg/24h | PATCH | TRANSDERMAL | ANDA074612 | Apotex Corp. | 66505-7093 | Nicotine | NICOTINE | HUMAN DRUG |
| Nicotine Transdermal System | 66505-7064-0 | 7 mg/24h | PATCH, EXTENDED RELEASE | TRANSDERMAL | ANDA074612 | Apotex Corp | 66505-7064 | Nicotine Transdermal System | NICOTINE | HUMAN DRUG |
| Nicotine Transdermal System | 66505-7088-0 | 7 mg/24h | PATCH, EXTENDED RELEASE | TRANSDERMAL | ANDA074612 | Apotex Corp. | 66505-7088 | Nicotine Transdermal System | NICOTINE | HUMAN DRUG |
| Nicotine Transdermal System | 66505-7089-0 | 14 mg/24h | PATCH, EXTENDED RELEASE | TRANSDERMAL | ANDA074612 | Apotex Corp. | 66505-7089 | Nicotine Transdermal System | NICOTINE | HUMAN DRUG |
| Nicotine Transdermal System | 66505-7090-0 | 21 mg/24h | PATCH, EXTENDED RELEASE | TRANSDERMAL | ANDA074612 | Apotex Corp. | 66505-7090 | Nicotine Transdermal System | NICOTINE | HUMAN DRUG |

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|---|---|---|---|---|---|---|---|---|---|---|
| Olanzapine | 60505-3110-8 | 2.5 mg/1 | TABLET, FILM COATED | ORAL | ANDA090798 | Apotex Corp. | 60505-3110 | Olanzapine | OLANZAPINE | HUMAN PRESCRIPTION DRUG |
| Olanzapine | 60505-3111-8 | 5 mg/1 | TABLET, FILM COATED | ORAL | ANDA090798 | Apotex Corp. | 60505-3111 | Olanzapine | OLANZAPINE | HUMAN PRESCRIPTION DRUG |
| Olanzapine | 60505-3114-8 | 10 mg/1 | TABLET, FILM COATED | ORAL | ANDA090798 | Apotex Corp. | 60505-3114 | Olanzapine | OLANZAPINE | HUMAN PRESCRIPTION DRUG |
| Olanzapine | 60505-3112-8 | 7.5 mg/1 | TABLET, FILM COATED | ORAL | ANDA090798 | Apotex Corp. | 60505-3112 | Olanzapine | OLANZAPINE | HUMAN PRESCRIPTION DRUG |
| Olanzapine | 60505-3114-9 | 10 mg/1 | TABLET, FILM COATED | ORAL | ANDA090798 | Apotex Corp. | 60505-3114 | Olanzapine | OLANZAPINE | HUMAN PRESCRIPTION DRUG |
| Olanzapine | 60505-3114-3 | 10 mg/1 | TABLET, FILM COATED | ORAL | ANDA090798 | Apotex Corp. | 60505-3114 | Olanzapine | OLANZAPINE | HUMAN PRESCRIPTION DRUG |
| Olanzapine | 60505-3140-3 | 20 mg/1 | TABLET, FILM COATED | ORAL | ANDA090798 | Apotex Corp. | 60505-3140 | Olanzapine | OLANZAPINE | HUMAN PRESCRIPTION DRUG |
| Olanzapine | 60505-3276-8 | 10 mg/1 | TABLET, ORALLY DISINTEGRATING | ORAL | ANDA091265 | Apotex Corp. | 60505-3276 | Olanzapine | OLANZAPINE | HUMAN PRESCRIPTION DRUG |
| Olanzapine | 60505-3278-8 | 20 mg/1 | TABLET, ORALLY DISINTEGRATING | ORAL | ANDA091265 | Apotex Corp. | 60505-3278 | Olanzapine | OLANZAPINE | HUMAN PRESCRIPTION DRUG |
| Olopatadine hydrochloride | 60505-6221-0 | 1 mg/mL | SOLUTION/ DROPS | OPHTHALMIC | ANDA078350 | Apotex Corp. | 60505-6221 | Olopatadine hydrochloride | OLOPATADINE HYDROCHLORIDE | HUMAN DRUG |
| Olopatadine hydrochloride | 60505-6222-3 | 2 mg/mL | SOLUTION/ DROPS | OPHTHALMIC | ANDA090918 | Apotex Corp. | 60505-6222 | Olopatadine hydrochloride | OLOPATADINE HYDROCHLORIDE | HUMAN DRUG |

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|---|---|---|---|---|---|---|---|---|---|---|
| Olopatadine Hydrochloride | 60505-0575-1 | 1 mg/mL | SOLUTION/ DROPS | OPHTHALMIC | ANDA078350 | Apotex Corp. | 60505-0575 | Olopatadine Hydrochloride | OLOPATADINE HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| Olopatadine Hydrochloride | 60505-0845-1 | 665 ug/1 | SPRAY, METERED | NASAL | ANDA091872 | Apotex Corp. | 60505-0845 | olopatadine hydrochloride | OLOPATADINE HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| Olopatadine Hydrochloride | 60505-0586-1 | 2 mg/mL | SOLUTION | OPHTHALMIC | ANDA090918 | Apotex Corp. | 60505-0586 | Olopatadine Hydrochloride | OLOPATADINE HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| Omega-3-acid ethyl esters | 60505-3179-7 | 1 g/1 | CAPSULE, LIQUID FILLED | ORAL | ANDA090973 | Apotex Corp. | 60505-3179 | Omega-3-acid ethyl esters | OMEGA-3-ACID ETHYL ESTERS | HUMAN PRESCRIPTION DRUG |
| Omega-3-acid ethyl esters | 60505-3179-3 | 1 g/1 | CAPSULE, LIQUID FILLED | ORAL | ANDA090973 | Apotex Corp. | 60505-3179 | Omega-3-acid ethyl esters | OMEGA-3-ACID ETHYL ESTERS | HUMAN PRESCRIPTION DRUG |
| Omega-3-acid ethyl esters | 60505-4463-7 | 1 g/1 | CAPSULE, LIQUID FILLED | ORAL | ANDA090973 | Apotex Corp. | 60505-4463 | Omega-3-acid ethyl esters | OMEGA-3-ACID ETHYL ESTERS | HUMAN PRESCRIPTION DRUG |
| Omega-3-acid ethyl esters | 60505-3179-6 | 1 g/1 | CAPSULE, LIQUID FILLED | ORAL | ANDA090973 | Apotex Corp. | 60505-3179 | Omega-3-acid ethyl esters | OMEGA-3-ACID ETHYL ESTERS | HUMAN PRESCRIPTION DRUG |
| Omeprazole | 60505-0065-2 | 20 mg/1 | CAPSULE, DELAYED RELEASE | ORAL | ANDA078043 | Apotex Corp | 60505-0865 | Omeprazole | OMEPRAZOLE | HUMAN PRESCRIPTION DRUG |
| Omeprazole | 60505-0065-8 | 20 mg/1 | CAPSULE, DELAYED RELEASE | ORAL | ANDA078043 | Apotex Corp | 60505-0865 | Omeprazole | OMEPRAZOLE | HUMAN PRESCRIPTION DRUG |
| Omeprazole | 60505-0145-2 | 10 mg/1 | CAPSULE, DELAYED RELEASE | ORAL | ANDA078043 | Apotex Corp | 60505-0143 | Omeprazole | OMEPRAZOLE | HUMAN PRESCRIPTION DRUG |
| Omeprazole | 60505-0146-1 | 40 mg/1 | CAPSULE, DELAYED RELEASE | ORAL | ANDA078043 | Apotex Corp | 60505-0146 | Omeprazole | OMEPRAZOLE | HUMAN PRESCRIPTION DRUG |
| Omeprazole | 60505-0146-2 | 40 mg/1 | CAPSULE, DELAYED RELEASE | ORAL | ANDA078043 | Apotex Corp | 60505-0146 | Omeprazole | OMEPRAZOLE | HUMAN PRESCRIPTION DRUG |

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|---|---|---|---|---|---|---|---|---|---|---|
| PAROXETINE | 60505-6097-4 | 10 mg/1 | TABLET, FILM COATED | ORAL | ANDA075356 | Apotex Corp. | 60505-6097 | paroxetine hydrochloride | PAROXETINE HYDROCHLORIDE ANHYDROUS | HUMAN PRESCRIPTION DRUG |
| PAROXETINE | 60505-6084-1 | 30 mg/1 | TABLET, FILM COATED | ORAL | ANDA075356 | Apotex Corp. | 60505-6084 | paroxetine hydrochloride | PAROXETINE HYDROCHLORIDE ANHYDROUS | HUMAN PRESCRIPTION DRUG |
| PAROXETINE | 60505-6093-1 | 10 mg/1 | TABLET, FILM COATED | ORAL | ANDA075356 | Apotex Corp. | 60505-6097 | paroxetine hydrochloride | PAROXETINE HYDROCHLORIDE ANHYDROUS | HUMAN PRESCRIPTION DRUG |
| PAROXETINE | 60505-6101-2 | 40 mg/1 | TABLET, FILM COATED | ORAL | ANDA075356 | Apotex Corp. | 60505-6101 | paroxetine hydrochloride | PAROXETINE HYDROCHLORIDE ANHYDROUS | HUMAN PRESCRIPTION DRUG |
| PAROXETINE | 60505-6084-4 | 30 mg/1 | TABLET, FILM COATED | ORAL | ANDA075356 | Apotex Corp. | 60505-6084 | paroxetine hydrochloride | PAROXETINE HYDROCHLORIDE ANHYDROUS | HUMAN PRESCRIPTION DRUG |
| PAROXETINE | 60505-6101-1 | 40 mg/1 | TABLET, FILM COATED | ORAL | ANDA077354 | Apotex Corp | 60505-6101 | paroxetine hydrochloride | PAROXETINE HYDROCHLORIDE ANHYDROUS | HUMAN PRESCRIPTION DRUG |
| PAROXETINE HYDROCHLORIDE | 60505-1316-3 | 12.5 mg/1 | TABLET, FILM COATED, EXTENDED RELEASE | ORAL | NDA022936 | Apotex Corp | 60505-1316 | paroxetine hydrochloride | PAROXETINE HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| PAROXETINE HYDROCHLORIDE | 60505-1317-3 | 25 mg/1 | TABLET, FILM COATED, EXTENDED RELEASE | ORAL | NDA022936 | Apotex Corp | 60505-1317 | paroxetine hydrochloride | PAROXETINE HYDROCHLORIDE HEMIHYDRATE | HUMAN PRESCRIPTION DRUG |
| PAROXETINE HYDROCHLORIDE | 60505-1318-3 | 37.5 mg/1 | TABLET, FILM COATED, EXTENDED RELEASE | ORAL | NDA022936 | Apotex Corp | 60505-1318 | paroxetine hydrochloride | PAROXETINE HYDROCHLORIDE HEMIHYDRATE | HUMAN PRESCRIPTION DRUG |
| PAROXETINE HYDROCHLORIDE | 60505-3675-7 | 37.5 mg/1 | TABLET, FILM COATED, EXTENDED RELEASE | ORAL | NDA022936 | Apotex Corp | 60505-3675 | paroxetine hydrochloride | PAROXETINE HYDROCHLORIDE HEMIHYDRATE | HUMAN PRESCRIPTION DRUG |
| PAXIL | 60505-0402-8 | 10 mg/5mL | SUSPENSION | ORAL | NDA020710 | Apotex Corp | 60505-0402 | paroxetine hydrochloride | PAROXETINE HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| PAXIL | 60505-4377-2 | 12.5 mg/1 | TABLET, FILM COATED, EXTENDED RELEASE | ORAL | NDA020936 | Apotex Corp | 60505-4377 | paroxetine hydrochloride | PAROXETINE HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| PAXIL | 60505-4378-3 | 25 mg/1 | TABLET, FILM COATED, EXTENDED RELEASE | ORAL | NDA020936 | Apotex Corp | 60505-4378 | paroxetine hydrochloride | PAROXETINE HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |

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|---|---|---|---|---|---|---|---|---|---|---|
| PAXIL | 60505-4378-3 | 37.5 mg/1 | TABLET, FILM COATED, EXTENDED RELEASE | ORAL | NDA020936 | Apotex Corp | 60505-4378 | paroxetine hydrochloride | PAROXETINE HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| PAXIL | 60505-4517-3 | 10 mg/1 | TABLET, FILM COATED | ORAL | NDA020031 | Apotex Corp | 60505-4517 | paroxetine hydrochloride | PAROXETINE HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| PAXIL | 60505-4518-3 | 20 mg/1 | TABLET, FILM COATED | ORAL | NDA020031 | Apotex Corp | 60505-4518 | paroxetine hydrochloride | PAROXETINE HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| PAXIL | 60505-4519-3 | 30 mg/1 | TABLET, FILM COATED | ORAL | NDA020031 | Apotex Corp | 60505-4519 | paroxetine hydrochloride | PAROXETINE HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| PAXIL | 60505-4520-3 | 40 mg/1 | TABLET, FILM COATED | ORAL | NDA020031 | Apotex Corp | 60505-4520 | paroxetine hydrochloride | PAROXETINE HYDROCHLORIDE | HUMAN PRESCRIPTION DRUG |
| Pemetrexed | 60505-6065-0 | 100 mg/4mL | INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS | ANDA203774 | Apotex Corp | 60505-6061 | Pemetrexed disodium | PEMETREXED DISODIUM | HUMAN PRESCRIPTION DRUG |
| Pemetrexed | 60505-6064-0 | 500 mg/20mL | INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS | ANDA203774 | Apotex Corp | 60505-6064 | Pemetrexed disodium | PEMETREXED DISODIUM | HUMAN PRESCRIPTION DRUG |
| Pemetrexed | 60505-6067-0 | 1000 mg/40mL | INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS | ANDA209085 | Apotex Corp | 60505-6067 | Pemetrexed disodium | PEMETREXED DISODIUM | HUMAN PRESCRIPTION DRUG |
| Pemetrexed | 60505-6066-0 | 750 mg/30mL | INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION | INTRAVENOUS | ANDA209085 | Apotex Corp | 60505-6066 | Pemetrexed disodium | PEMETREXED DISODIUM | HUMAN PRESCRIPTION DRUG |
| Penicillamine | 60505-4696-1 | 250 mg/1 | CAPSULE | ORAL | ANDA213310 | Apotex Corp. | 60505-4696 | Penicillamine | PENICILLAMINE | HUMAN PRESCRIPTION DRUG |
| PENTOXIFYLLINE | 60505-0833-8 | 400 mg/1 | TABLET, EXTENDED RELEASE | ORAL | ANDA075191 | Apotex Corp. | 60505-0833 | PENTOXIFYLLINE | PENTOXIFYLLINE | HUMAN PRESCRIPTION DRUG |
| PENTOXIFYLLINE | 60505-0833-7 | 400 mg/1 | TABLET, EXTENDED RELEASE | ORAL | ANDA075191 | Apotex Corp. | 60505-0833 | PENTOXIFYLLINE | PENTOXIFYLLINE | HUMAN PRESCRIPTION DRUG |
| PENTOXIFYLLINE | 60505-0833-6 | 400 mg/1 | TABLET, EXTENDED RELEASE | ORAL | ANDA075191 | Apotex Corp. | 60505-0833 | PENTOXIFYLLINE | PENTOXIFYLLINE | HUMAN PRESCRIPTION DRUG |
| PENTOXIFYLLINE | 60505-0833-8 | 400 mg/1 | TABLET, EXTENDED RELEASE | ORAL | ANDA075191 | Apotex Corp. | 60505-0833 | PENTOXIFYLLINE | PENTOXIFYLLINE | HUMAN PRESCRIPTION DRUG |

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|---|---|---|---|---|---|---|---|---|---|---|
| + Pregabalin | 60505-3799-9 | 225 mg/1 | CAPSULE | ORAL | ANDA211685 | ApotexCorp | 60505-3799 | Pregabalin | PREGABALIN | HUMAN PRESC DRUG |
| + Pregabalin | 60505-3800-8 | 300 mg/1 | CAPSULE | ORAL | ANDA211685 | ApotexCorp | 60505-3800 | Pregabalin | PREGABALIN | HUMAN PRESC DRUG |
| + Regadenoson | 60505-6116-0 | .08 mg/mL | INJECTION, SOLUTION | INTRAVENOUS | ANDA207164 | Apotex Corp. | 60505-6116 | regadenoson | REGADENOSON | HUMAN PRESC DRUG |
| + Risedronate Sodium | 60505-3163-0 | 35 mg/1 | TABLET, FILM COATED | ORAL | ANDA090877 | Apotex Corp. | 60505-3163 | Risedronate Sodium | RISEDRONATE SODIUM | HUMAN PRESC DRUG |
| + Risedronate Sodium | 60505-3161-2 | 35 mg/1 | TABLET, FILM COATED | ORAL | ANDA090877 | Apotex Corp. | 60505-3161 | Risedronate Sodium | RISEDRONATE SODIUM | HUMAN PRESC DRUG |
| + Risedronate Sodium | 60505-3096-2 | 75 mg/1 | TABLET, FILM COATED | ORAL | ANDA090877 | Apotex Corp. | 60505-3096 | Risedronate Sodium | RISEDRONATE SODIUM | HUMAN PRESC DRUG |
| + Risedronate Sodium | 60505-3097-2 | 150 mg/1 | TABLET, FILM COATED | ORAL | ANDA090877 | Apotex Corp. | 60505-3097 | Risedronate Sodium | RISEDRONATE SODIUM | HUMAN PRESC DRUG |
| + Risedronate Sodium | 60505-3097-4 | 150 mg/1 | TABLET, FILM COATED | ORAL | ANDA090877 | Apotex Corp. | 60505-3097 | Risedronate Sodium | RISEDRONATE SODIUM | HUMAN PRESC DRUG |
| + SELEGILINE HYDROCHLORIDE | 60505-0055-2 | 5 mg/1 | CAPSULE | ORAL | ANDA075321 | Apotex Corp. | 60505-0055 | SELEGILINE HYDROCHLORIDE | SELEGILINE HYDROCHLORIDE | HUMAN PRESC DRUG |
| + Selegiline Hydrochloride | 60505-3438-8 | 5 mg/1 | TABLET | ORAL | ANDA074871 | Apotex Corp. | 60505-3438 | Selegiline Hydrochloride | SELEGILINE HYDROCHLORIDE | HUMAN PRESC DRUG |
| + SELEGILINE HYDROCHLORIDE | 60505-0055-1 | 5 mg/1 | CAPSULE | ORAL | ANDA075321 | Apotex Corp. | 60505-0055 | SELEGILINE HYDROCHLORIDE | SELEGILINE HYDROCHLORIDE | HUMAN PRESC DRUG |
| + SELEGILINE HYDROCHLORIDE | 60505-0063-9 | 5 mg/1 | CAPSULE | ORAL | ANDA075321 | Apotex Corp. | 60505-0063 | SELEGILINE HYDROCHLORIDE | SELEGILINE HYDROCHLORIDE | HUMAN PRESC DRUG |
| + Selegiline Hydrochloride | 60505-3438-3 | 5 mg/1 | TABLET | ORAL | ANDA074871 | Apotex Corp. | 60505-3438 | Selegiline Hydrochloride | SELEGILINE HYDROCHLORIDE | HUMAN PRESC DRUG |
| + Sirolimus | 60505-6197-2 | 1 mg/mL | SOLUTION | ORAL | ANDA211406 | Apotex Corp | 60505-6197 | SIROLIMUS | SIROLIMUS | HUMAN PRESC DRUG |

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| Proprietary Name | NDC Package Code | Strength | Dosage Form | Route | Appl. No. | Labeler Name | Product NDC | Nonproprietary Name | Substance Name | Prod Type |
|---|---|---|---|---|---|---|---|---|---|---|
| + Solifenacin Succinate | 60505-4782-3 | 5 mg/1 | TABLET, FILM COATED | ORAL | ANDA209233 | Apotex Corp. | 60505-4782 | Solifenacin Succinate | SOLIFENACIN SUCCINATE | HUMAN PRESC DRUG |
| + Solifenacin Succinate | 60505-4783-3 | 10 mg/1 | TABLET, FILM COATED | ORAL | ANDA209233 | Apotex Corp. | 60505-4783 | Solifenacin Succinate | SOLIFENACIN SUCCINATE | HUMAN PRESC DRUG |
| + Sotalol Hydrochloride | 60505-0082-1 | 240 mg/1 | TABLET | ORAL | ANDA076142 | Apotex Corp. | 60505-0082 | Sotalol Hydrochloride | SOTALOL HYDROCHLORIDE | HUMAN PRESC DRUG |
| + Sotalol Hydrochloride | 60505-0080-1 | 80 mg/1 | TABLET | ORAL | ANDA076142 | Apotex Corp. | 60505-0080 | Sotalol Hydrochloride | SOTALOL HYDROCHLORIDE | HUMAN PRESC DRUG |
| + Sotalol Hydrochloride | 60505-0224-1 | 160 mg/1 | TABLET | ORAL | ANDA076214 | Apotex Corp. | 60505-0224 | Sotalol Hydrochloride | SOTALOL HYDROCHLORIDE | HUMAN PRESC DRUG |
| + Sotalol Hydrochloride | 60505-0080-8 | 80 mg/1 | TABLET | ORAL | ANDA076143 | Apotex Corp. | 60505-0080 | Sotalol Hydrochloride | SOTALOL HYDROCHLORIDE | HUMAN PRESC DRUG |
| + Sotalol Hydrochloride | 60505-0081-1 | 160 mg/1 | TABLET | ORAL | ANDA076143 | Apotex Corp. | 60505-0081 | Sotalol Hydrochloride | SOTALOL HYDROCHLORIDE | HUMAN PRESC DRUG |
| + Sotalol Hydrochloride | 60505-0159-8 | 120 mg/1 | TABLET | ORAL | ANDA076142 | Apotex Corp. | 60505-0159 | Sotalol Hydrochloride | SOTALOL HYDROCHLORIDE | HUMAN PRESC DRUG |
| + Sotalol Hydrochloride | 60505-0224-2 | 160 mg/1 | TABLET | ORAL | ANDA076214 | Apotex Corp. | 60505-0224 | Sotalol Hydrochloride | SOTALOL HYDROCHLORIDE | HUMAN PRESC DRUG |
| + Sotalol Hydrochloride | 60505-0159-1 | 120 mg/1 | TABLET | ORAL | ANDA076143 | Apotex Corp. | 60505-0159 | Sotalol Hydrochloride | SOTALOL HYDROCHLORIDE | HUMAN PRESC DRUG |
| + Sotalol Hydrochloride | 60505-0222-2 | 80 mg/1 | TABLET | ORAL | ANDA076214 | Apotex Corp. | 60505-0222 | Sotalol Hydrochloride | SOTALOL HYDROCHLORIDE | HUMAN PRESC DRUG |
| + Sotalol Hydrochloride | 60505-0223-1 | 120 mg/1 | TABLET | ORAL | ANDA076214 | Apotex Corp. | 60505-0223 | Sotalol Hydrochloride | SOTALOL HYDROCHLORIDE | HUMAN PRESC DRUG |
| + Sotalol Hydrochloride | 60505-0222-1 | 80 mg/1 | TABLET | ORAL | ANDA076214 | Apotex Corp. | 60505-0222 | Sotalol Hydrochloride | SOTALOL HYDROCHLORIDE | HUMAN PRESC DRUG |
| + Sotalol Hydrochloride | 60505-0223-2 | 120 mg/1 | TABLET | ORAL | ANDA076214 | Apotex Corp. | 60505-0223 | Sotalol Hydrochloride | SOTALOL HYDROCHLORIDE | HUMAN PRESC DRUG |
| + Sotalol Hydrochloride | 60505-0081-0 | 160 mg/1 | TABLET | ORAL | ANDA076143 | Apotex Corp. | 60505-0081 | Sotalol Hydrochloride | SOTALOL HYDROCHLORIDE | HUMAN PRESC DRUG |
| + Sotalol Hydrochloride | 60505-0082-0 | 240 mg/1 | TABLET | ORAL | ANDA076143 | Apotex Corp. | 60505-0082 | Sotalol Hydrochloride | SOTALOL HYDROCHLORIDE | HUMAN PRESC DRUG |
| + Tenofovir Disoproxil Fumarate | 60505-4466-3 | 300 mg/1 | TABLET, COATED | ORAL | ANDA209498 | Apotex Corp. | 60505-4466 | Tenofovir Disoproxil Fumarate | TENOFOVIR DISOPROXIL FUMARATE | HUMAN PRESC DRUG |

Top (https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm)

| Proprietary Name | NDC Package Code | Strength | Dosage Form | Route | Appl. No. | Labeler Name | Product NDC | Nonproprietary Name | Substance Name | Pharm Class | DEA Schedule | Product Type |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Trazodone Hydrochloride | 60505-2589-1 | 300 mg/1 | TABLET | ORAL | ANDA071196 | Apotex Corp | 60505-2589 | Trazodone Hydrochloride | TRAZODONE HYDROCHLORIDE | | | HUMAN PRESCRIPTION DRUG |
| Trazodone Hydrochloride | 60505-2584-1 | 100 mg/1 | TABLET | ORAL | ANDA071196 | Apotex Corp | 60505-2584 | Trazodone Hydrochloride | TRAZODONE HYDROCHLORIDE | | | HUMAN PRESCRIPTION DRUG |
| Trazodone Hydrochloride | 60505-2589-6 | 300 mg/1 | TABLET | ORAL | ANDA071196 | Apotex Corp | 60505-2589 | Trazodone Hydrochloride | TRAZODONE HYDROCHLORIDE | | | HUMAN PRESCRIPTION DRUG |
| Trazodone Hydrochloride | 60505-2584-7 | 100 mg/1 | TABLET | ORAL | ANDA071196 | Apotex Corp | 60505-2584 | Trazodone Hydrochloride | TRAZODONE HYDROCHLORIDE | | | HUMAN PRESCRIPTION DRUG |
| Trazodone Hydrochloride | 60505-2585-1 | 150 mg/1 | TABLET | ORAL | ANDA071196 | Apotex Corp | 60505-2585 | Trazodone Hydrochloride | TRAZODONE HYDROCHLORIDE | | | HUMAN PRESCRIPTION DRUG |
| Trazodone Hydrochloride | 60505-2585-7 | 150 mg/1 | TABLET | ORAL | ANDA071196 | Apotex Corp | 60505-2585 | Trazodone Hydrochloride | TRAZODONE HYDROCHLORIDE | | | HUMAN PRESCRIPTION DRUG |
| Trazodone Hydrochloride | 60505-2653-1 | 50 mg/1 | TABLET | ORAL | ANDA071258 | Apotex Corp | 60505-2653 | Trazodone Hydrochloride | TRAZODONE HYDROCHLORIDE | | | HUMAN PRESCRIPTION DRUG |
| Trazodone Hydrochloride | 60505-2654-8 | 100 mg/1 | TABLET | ORAL | ANDA071196 | Apotex Corp | 60505-2654 | Trazodone Hydrochloride | TRAZODONE HYDROCHLORIDE | | | HUMAN PRESCRIPTION DRUG |
| Trazodone Hydrochloride | 60505-2653-7 | 50 mg/1 | TABLET | ORAL | ANDA071258 | Apotex Corp | 60505-2653 | Trazodone Hydrochloride | TRAZODONE HYDROCHLORIDE | | | HUMAN PRESCRIPTION DRUG |
| Trazodone Hydrochloride | 60505-2661-8 | 150 mg/1 | TABLET | ORAL | ANDA071196 | Apotex Corp | 60505-2661 | Trazodone Hydrochloride | TRAZODONE HYDROCHLORIDE | | | HUMAN PRESCRIPTION DRUG |
| Trazodone Hydrochloride | 60505-4089-3 | 150 mg/1 | TABLET | ORAL | ANDA071196 | Apotex Corp | 60505-4089 | Trazodone Hydrochloride | TRAZODONE HYDROCHLORIDE | | | HUMAN PRESCRIPTION DRUG |
| Trazodone Hydrochloride | 60505-2599-7 | 300 mg/1 | TABLET | ORAL | ANDA071196 | Apotex Corp | 60505-2599 | Trazodone Hydrochloride | TRAZODONE HYDROCHLORIDE | | | HUMAN PRESCRIPTION DRUG |
| Trazodone Hydrochloride | 60505-2653-1 | 50 mg/1 | TABLET | ORAL | ANDA071258 | Apotex Corp | 60505-2653 | Trazodone Hydrochloride | TRAZODONE HYDROCHLORIDE | | | HUMAN PRESCRIPTION DRUG |
| Trazodone Hydrochloride | 60505-2654-8 | 100 mg/1 | TABLET | ORAL | ANDA071196 | Apotex Corp | 60505-2654 | Trazodone Hydrochloride | TRAZODONE HYDROCHLORIDE | | | HUMAN PRESCRIPTION DRUG |
| Trimethoprim and Hydrochlorothiazide | 60505-2566-8 | 25 mg/1, 37.5 mg/1 | TABLET | ORAL | ANDA071251 | Apotex Corp. | 60505-2566 | Trimethoprim and Hydrochlorothiazide | HYDROCHLOROTHIAZIDE; TRIAMTERENE | | | HUMAN PRESCRIPTION DRUG |
| Trimethoprim and Hydrochlorothiazide | 60505-2567-1 | 50 mg/1, 75 mg/1 | TABLET | ORAL | ANDA071251 | Apotex Corp. | 60505-2567 | Trimethoprim and Hydrochlorothiazide | HYDROCHLOROTHIAZIDE; TRIAMTERENE | | | HUMAN PRESCRIPTION DRUG |
| Trimethoprim and Hydrochlorothiazide | 60505-2567-7 | 50 mg/1, 75 mg/1 | TABLET | ORAL | ANDA071251 | Apotex Corp. | 60505-2567 | Trimethoprim and Hydrochlorothiazide | HYDROCHLOROTHIAZIDE; TRIAMTERENE | | | HUMAN PRESCRIPTION DRUG |

Yes (https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm)





| Proprietary Name | NDC Package Code | Strength | Dosage Form | Route | Appl. No. | Labeler Name | Product NDC | Nonproprietary Name | Substance Name | Pharm Class | DEA Schedule | Product Type |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Trimethoprim and Hydrochlorothiazide | 60505-2566-7 | 25 mg/1, 37.5 mg/1 | TABLET | ORAL | ANDA071251 | Apotex Corp. | 60505-2566 | Trimethoprim and Hydrochlorothiazide | HYDROCHLOROTHIAZIDE; TRIAMTERENE | | | HUMAN PRESCRIPTION DRUG |
| Trimethoprim and Hydrochlorothiazide | 60505-2567-1 | 50 mg/1, 75 mg/1 | TABLET | ORAL | ANDA071251 | Apotex Corp. | 60505-2567 | Trimethoprim and Hydrochlorothiazide | HYDROCHLOROTHIAZIDE; TRIAMTERENE | | | HUMAN PRESCRIPTION DRUG |
| Trimethoprim and Hydrochlorothiazide | 60505-2566-1 | 25 mg/1, 37.5 mg/1 | TABLET | ORAL | ANDA071251 | Apotex Corp. | 60505-2566 | Trimethoprim and Hydrochlorothiazide | HYDROCHLOROTHIAZIDE; TRIAMTERENE | | | HUMAN PRESCRIPTION DRUG |
| VARENICLINE | 60505-3613-6 | .5 mg/1 | TABLET, FILM COATED | ORAL | ANDA201963 | Apotex Corp | 60505-3613 | VARENICLINE | VARENICLINE TARTRATE | | | HUMAN PRESCRIPTION DRUG |
| VARENICLINE | 60505-3614-3 | 1 mg/1 | TABLET, FILM COATED | ORAL | ANDA201963 | Apotex Corp | 60505-3614 | VARENICLINE | VARENICLINE TARTRATE | | | HUMAN PRESCRIPTION DRUG |
| Vilazodone | 60505-4772-3 | 10 mg/1 | TABLET | ORAL | NDA022567 | Apotex Corp | 60505-4772 | Vilazodone Hydrochloride | VILAZODONE HYDROCHLORIDE | | | HUMAN PRESCRIPTION DRUG |
| Vilazodone | 60505-4773-3 | 20 mg/1 | TABLET | ORAL | NDA022567 | Apotex Corp | 60505-4773 | Vilazodone Hydrochloride | VILAZODONE HYDROCHLORIDE | | | HUMAN PRESCRIPTION DRUG |
| Vilazodone | 60505-4774-3 | 40 mg/1 | TABLET | ORAL | NDA022567 | Apotex Corp | 60505-4774 | Vilazodone Hydrochloride | VILAZODONE HYDROCHLORIDE | | | HUMAN PRESCRIPTION DRUG |
| Ziprasidone hydrochloride | 60505-2528-6 | 20 mg/1 | CAPSULE | ORAL | ANDA077561 | Apotex Corp. | 60505-2528 | Ziprasidone HCl | ZIPRASIDONE HYDROCHLORIDE | | | HUMAN PRESCRIPTION DRUG |
| Ziprasidone hydrochloride | 60505-2530-6 | 60 mg/1 | CAPSULE | ORAL | ANDA077561 | Apotex Corp. | 60505-2530 | Ziprasidone HCl | ZIPRASIDONE HYDROCHLORIDE | | | HUMAN PRESCRIPTION DRUG |
| Ziprasidone hydrochloride | 60505-2529-6 | 40 mg/1 | CAPSULE | ORAL | ANDA077561 | Apotex Corp. | 60505-2529 | Ziprasidone HCl | ZIPRASIDONE HYDROCHLORIDE | | | HUMAN PRESCRIPTION DRUG |
| Ziprasidone hydrochloride | 60505-2531-6 | 80 mg/1 | CAPSULE | ORAL | ANDA077561 | Apotex Corp. | 60505-2531 | Ziprasidone HCl | ZIPRASIDONE HYDROCHLORIDE | | | HUMAN PRESCRIPTION DRUG |

Showing 1 to 609 of 609 entries

Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.GOV)

See also: Drug Registration and Listing Instructions (https://www.fda.gov/DrugsGuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Yes (https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm)

NABP
National Association of Boards of Pharmacy

☐ Main Menu

# Accredited Drug Distributors

**Find an Accredited Drug Distributor**

4-19-23

Facility Name

State (All)

Search Reset

Current list of 1 NABP-Accredited Drug Distributors

Accreditation is valid for 3 years

Facilities listed with "Reaccreditation in process" remain accredited throughout the reaccreditation process.

| Name | Address | Accreditation Date |
|---|---|---|
| Apotex Corp | 2515 Airwest Blvd<br>Plainfield, IN 46168 | Reaccreditation in process |

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| NDC/NHR IC Labeler Code | Firm Name |
|---|---|
| 60505 | Apotex Corp. |

Verified 4-19-23 DB

APOTEX
ADVANCING GENERICS

## Corporate Officers

| | |
|---|---|
| Secretary, VP General Counsel US: | **Roberta Loomar**<br>Business Address: 2400 North Commerce Parkway Suite 400, Weston FL 33326 |
| VP, Sales & Marketing: | **Michael Bohling**<br>Business Address: 2400 North Commerce Parkway Suite 400, Weston FL 33326 |
| President & CEO: | **Peter Hardwick**<br>Business Address: 2400 North Commerce Parkway Suite 400, Weston FL 33326 |
| Sr. VP Global Regulatory Affairs: | **Kiran Krishnan**<br>Business Address: 2400 North Commerce Parkway Suite 400, Weston FL 33326 |

| | |
|---|---|
| • Ownership is 100% by Aposherm Delaware Holdings Corp. | • State of Incorporation is Delaware<br>• Federal Employer Identification Number 13-3661214 |

# Delaware

## The First State



I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "APOTEX CORP." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SEVENTEENTH DAY OF JANUARY, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "APOTEX CORP." WAS INCORPORATED ON THE NINTH DAY OF APRIL, A.D. 1992.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

2293995 8300

SR# 20230152189

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202505217

Date: 01-17-23

Indiana Professional Licensing Agency
Indiana Board of Pharmacy
402 W. Washington Street, W072
Indianapolis, IN 46204

## Wholesale Drug Distributor

| License Number | Expire Date |
|---|---|
| 48000970A | 09/30/2024 |

Apotex Corp.

Eric J. Holcomb
Governor
State of Indiana

Deborah J. Frye
Executive Director
Indiana Professional Licensing Agency

Indiana Professional Licensing Agency
402 W. Washington Street, W072
Indianapolis, IN 46204

Wholesale Drug Distributor

| License Number | Expire Date |
|---|---|
| 48000970A | 09/30/2024 |

Apotex Corp.

Signature _____

# State of Indiana

## DEMOGRAPHIC INFORMATION

Name: Apotex Corp.

## ADDRESS INFORMATION

Line 1:
Line 2: 2516 Airwest Blvd
City/State/Zip: Plainfield IN 46168
County: Hendricks

## LICENSE INFORMATION

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Lic #: | 48000970A | Profession: | Pharmacy Board | Type: | Wholesale Drug Distributor | Secondary: | |
| Status: | Active | Issued: | 9/14/2000 | Expiration: | 9/30/2024 | | |
| Method: | Application | | | | | | |

## DISCIPLINE INFORMATION

-

## RELATED LICENSES

No Related Licenses

Indiana Professional Licensing Agency
Indiana Board of Pharmacy
402 W. Washington Street, W072
Indianapolis, IN 46204

# CSR

| Registration Number | Expire Date |
|---|---|
| 62100032B | 12/31/2023 |

## DRUG SCHEDULES

| 1 | 2 | 2N | 3 | 3N | 4 | 5 |
|---|---|---|---|---|---|---|
| | | | Yes | Yes | Yes | Yes |

Apotex Corp.
2516 Airwest Blvd
Plainfield IN 46168

Eric J. Holcomb
Governor
State of Indiana

Deborah J. Frye
Executive Director
Indiana Professional Licensing Agency

Indiana Professional Licensing Agency
402 W. Washington Street, W072
Indianapolis, IN 46204

**CSR**

| Registration Number | Expire Date |
|---|---|
| 62100032B | 12/31/2023 |

**Apotex Corp.**

Signature

# State of Indiana

## DEMOGRAPHIC INFORMATION

Name: Apotex Corp.

## ADDRESS INFORMATION

Line 1: 2516 Airwest Blvd
Line 2:
City/State/Zip: Plainfield IN 46168
County: Hendricks

## LICENSE INFORMATION

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Lic #: | 62100032B | Profession: | Pharmacy Board | Type: | CSR | Secondary: | Wholesale Distributor |
| Status: | Active | Issued: | 1/31/2005 | Expiration: | 12/31/2023 | | |
| Method: | Application | | | | | | |

## DISCIPLINE INFORMATION

-

## RELATED LICENSES

No Related Licenses

## LICENSE CSR INFORMATION

| | | | | | |
|---|---|---|---|---|---|
| Drug Schedule 1: | No | Drug Schedule 2: | No | Drug Schedule 2n: | No |
| Drug Schedule 3: | Yes | Drug Schedule 3n: | Yes | Drug Schedule 4: | Yes |
| Drug Schedule 5: | Yes | | | | |

## INSPECTION INFORMATION

| | | |
|---|---|---|
| Inspection Type: Controlled Substances Inspection Report | Inspection Date: 4/6/2011 | Inspection Grade: Pass |
| Inspection Type: Controlled Substances Inspection Report | Inspection Date: 11/9/2012 | Inspection Grade: Pass |
| Inspection Type: Controlled Substances Inspection Report | Inspection Date: 2/17/2017 | Inspection Grade: Pass |
| Inspection Type: Controlled Substances Inspection Report | Inspection Date: 8/19/2014 | Inspection Grade: Pass |
| Inspection Type: Controlled Substances Inspection Report | Inspection Date: 5/3/2021 | Inspection Grade: Pass |
| Inspection Type: Controlled Substances Inspection Report | Inspection Date: | Inspection Grade: |

TOKIO MARINE HCC

American Contractors Indemnity Company
6900 E. Camelback Rd., Ste 610 Scottsdale, AZ 85251
main 623 931 3911 facsimile 623 931 3910

June 21, 2023

# Surety Rider

To be attached to and from a part of **MISC CLASS BONDS** (Type of Bond), Bond No. **288884**

In favor of **NEVADA STATE BOARD OF PHARMACY , ADDRESS : 431 W PLUMB LANE, RENO, NV 89509** (Obligee)

On behalf of **APOTEX CORPORATION, ADDRESS : 2400 N. COMMERCE PKWY #400, WESTON, FL 33326** (Principal)

Surety hereby gives its consent to amend principal's **OPERATING LOCATIONS** to read:

From: 2400 N. COMMERCE PKWY #400, WESTON, FL 33326

To: 2400 N. COMMERCE PKWY #400, WESTON, FL 33326
2516 AIRWEST BLVD, PLAINFIELD, IN 46168

To be effective: **06/20/2023**

Signed and sealed this **21** day of **JUNE, 2023**

**American Contractors Indemnity Company**

Kelli Linsted

KELLI LINSTED , Attorney-in-fact

Producer:
PROFESSIONAL BOND SPECIALISTS, INC.
9967 N 94TH LANE
PEORIA, AZ 85345

AMERICAN CONTRACTORS INDEMNITY CO. INCORPORATED SEPT. 25, 1990 CALIFORNIA

Obligee:
NEVADA STATE BOARD OF PHARMACY
431 W PLUMB LANE
RENO, NV 89509

NEVADA STATE BOARD OF PHARMACY
555 Double Eagle Court #1100
Reno, Nevada 89521
(775) 850-1440
Fax: (775) 850-1444

# PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 288884

Application/License No. _____

APOTEX CORP., doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
2400COMMERCE PKWY - STE. 400: WESTON, FL 33326, as
Address of Applicant/Principal
PRINCIPAL, and American Contractors Indemnity Company, a
Surety Company
corporation organized under the laws of the state of California
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
9841 Airport Blvd. 9th Floor; Los Angeles, CA 90045 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 23, 2006.
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal

may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.

(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.

(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.

(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.

(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.

(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.

(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 23rd day of October, 20 06.

APPLICANT/PRINCIPAL
APOTEX CORP.

Tammy McIntire
Authorized Representative

SURETY COMPANY
AMERICAN CONTRACTORS INDEMNITY COMPANY

Jean Paulus
Surety Company's Representative

Jean Paulus, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Deborah Veira
Witness

Malinda Bennett
Witness

SIGNED and SEALED in the presence of:

Lynn Marci
Witness

Denise Bishop
Witness

Countersigned by:

Therman Beavor
Nevada Resident Agent Therman Beavor
Agent Lic. No. 85442

State of Florida
County of Broward
The foregoing instrument was acknowledged before me this 23rd Day of Oct-2006 by Tammy McIntire who signed in the presence of witnesses.

Laurie Vaniska

LAURIE VANISKA
MY COMMISSION # DD 227945
EXPIRES: July 12, 2007
Bonded Thru Notary Public Underwriters

# American Contractors Indemnity Company

9841 Airport Blvd., 9th Floor Los Angeles, California 90045

## POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS:

That American Contractors Indemnity Company of the State of California, a California corporation, does hereby appoint,

**Jean Paulus, Lynn Macci or M. J. Hopper of Glendale, Arizona**

its true and lawful Attorney(s)-in-Fact, with full authority to execute on its behalf bonds, undertakings, recognizances and other contracts of indemnity and writings obligatory in the nature thereof, issued in the course of its business and to bind the Company thereby, in an Amount not to exceed $ **********3,000,000.00**********. This Power of Attorney shall expire without further action on March 18, 2007.

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of AMERICAN CONTRACTORS INDEMNITY COMPANY at a meeting duly called and held on the 6th day of December, 1990.

*"RESOLVED that the Chief Executive Officer, President or any Vice President, Executive Vice President, Secretary or Assistant Secretary, shall have the power and authority*

1. *To appoint Attorney(s)-in-Fact and to authorize them to execute on behalf of the Company, and attach the seal of the Company thereto, bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof and,*
2. *To remove, at any time, any such Attorney-in-Fact and revoke the authority given.*

*RESOLVED FURTHER, that the signatures of such officers and the seal of the Company may be affixed to any such Power of Attorney or certificate relating thereto by facsimile, and any such Power of Attorney or certificate bearing such facsimile signatures or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking to which it is attached."*

IN WITNESS WHEREOF, American Contractors Indemnity Company has caused its seal to be affixed hereto and executed by its Chief Executive Officer on the 15th day of December, 2003.

AMERICAN CONTRACTORS INDEMNITY COMPANY

By: _____
Robert F. Thomas, Chief Executive Officer

STATE OF CALIFORNIA §
COUNTY OF LOS ANGELES §

On this 15th day of December 2003, before me, Deborah Reese, a notary public, personally appeared Robert F. Thomas, Chief Executive Officer of American Contractors Indemnity Company, personally known to me (or proved to me on the basis of satisfactory evidence) to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

WITNESS my hand and official seal.

_____
Signature of Notary
My Commission expires March 18, 2007

DEBORAH REESE
Commission # 1406149
Notary Public - California
Los Angeles County
My Comm. Expires Mar 18, 2007

I, Jeannie J. Kim, Corporate Secretary of American Contractors Indemnity Company, do hereby certify that the Power of Attorney and the resolution adopted by the Board of Directors of said Company as set forth above, are true and correct transcripts thereof and that neither the said Power of Attorney nor the resolution have been revoked and they are now in full force and effect.

IN WITNESS HEREOF, I have hereunto set my hand this 23rd day of October, 2006.

_____
Jeannie J. Kim, Corporate Secretary

Bond No. 288884

Agency No. #9050

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

### Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Apotex Corp.

Pharmacy/Wholesaler License # (if applicable) WH01327

Physical Address 2516 Airwest Boulevard

City Plainfield State IN Zip 46168

Mailing Address (if different from physical address) 2516 Airwest Boulevard

City Plainfield State IN Zip 46168

Telephone (317) 839-6550 Website www.apotex.com/us/en/

Licensing Company Email sshaikh@apotexcorp.com

### Section 2: Personal Information

First Jeremy Middle D Last Rollins

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 2516 Airwest Blvd

City Plainfield State IN Zip 46168

Telephone 317-839-6550 ext 5014 Email jrollins@apotexcorp.com

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | x |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | x |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | x |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | x |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | x |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Devry Keller Graduate School of Management | | 08/09 - 06/11 | |
| **Address** | **City** | **State** | **Zip** |
| 9100 Keystone Crossing #350 | Indianapolis | IN | 46240 |
| **Diploma/Degree obtained, if any** | | | |
| MBA, Accounting and Finance | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| Indiana State University | | 08/96 - 06/20 | |
| **Address** | **City** | **State** | **Zip** |
| 200 N 7th St | Terre Haute | IN | 47809 |
| **Diploma/Degree obtained, if any** | | | |
| Bachelor of Science in Accounting | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| High School Diploma | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |
| **School Name** | | **From - To (MM/YY – MM/YY** | |
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 03/18 - Present | [redacted] Forreston Oak Dr. | Noblesville | IN | 46062 |
| 01/11 - 03/18 | [redacted] Long Walk Dr. | Noblesville | IN | 46060 |
| | | | | |
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**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Apotex Corp. | | | 05/20 - present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 2516 Airwest Boulevard | | Plainfield | IN | 46168 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| (317) 839-6550 | Site Lead, Associate Director | | 40/wk | |
| **Description of Duties** | | | | |
| See Resume | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | x |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | N/A |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | x |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | x |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | x |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | x |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | x |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | x |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | x |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | x |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # N/A . Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

Date

I, Jeremy Rollins, **certify that as the designated representative for**

Apotex Corp.,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jeremy Rollins

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

13 APR 23

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Jeremy Rollins

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

13 APR 23

Date

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**Please have this section completed in the presence of a Notary Public.**

State of Indiana, ss. County of Hendricks

I, Jeremy Rollins, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

13 APR 23

Date

Subscribed and Sworn to before me this 13 day of April.

Notary Public Signature

CASSANDRA MOWERY
Notary Public - Seal
Hendricks County - State of Indiana
Commission Number NP0747995
My Commission Expires Apr 2, 2031

# JEREMY ROLLINS, MBA, CPA, CPSM

[redacted] Forreston Oak Dr. • Noblesville, IN 46062 • [redacted] • [redacted]

*Site Lead/Associate Director*

PROJECT MANAGEMENT • WAREHOUSE, PROCUREMENT & LOGISTICS • CONTRACT NEGOTIATIONS
MANAGERIAL ACUMEN • MANPOWER PLANNING & SCHEDULING • COMMUNICATIONS

## SUMMARY OF QUALIFICATIONS

- Highly trained and professional Leader with an **MBA, CPA** and **Certified Professional in Supply Management**, skilled in Strategic Planning/Visioning along with Tactical Execution to implement global policies.
- Extensive Warehouse Management experience includes both the private sector and Government Agency leadership of large centralized and decentralized Supply Chain organizations.
- Project Management includes extensive travel in North America, China, Mexico, Europe, and the Middle East, with cross-functional and multi-cultural Team Leadership experience to implement global corporate strategies.
- Warehouse and Logistic experience includes direct accountability of corporate operations throughout North America.
- Extensive use of ERP including DAX, SAP, and Microsoft Office Products along with several Database applications.

## CAREER ACCOMPLISHMENTS

- Led multiple cross-functional teams that addressed unplanned production downtime, reduction in total waste, improved vendor lead times, improved cash flow, and reduction in corporate expenses.
- Introduced Total Quality Management principals. Develop key performance indicators that lead to improvements in Warehouse Safety, Capacity Utilization, Inventory Accuracy and Loss Reduction, Labor dollars, in addition to improving overall leadership accountability.
- Utilized Lean Manufacturing, Price to Price Negotiations and Kaizen Processes to improve visibility to spend and deliver cost savings targets.
- Recognized Corporate Leader through my ability to develop High-Performance Teams, create/execute Strategic vision, develop key performance indicators, and react to tactical Warehouse environments.

## PROFESSIONAL EXPERIENCE

**Distribution Center Assoc. Director | Site Lead** — May 2020 - Present
Apotex Corp. — Plainfield, IN

*Apotex Pharmaceuticals is an global generic pharmaceutical company that produces high quality, affordable medicines for patients around the world.*

- Site General Manager responsible for 50 employees operating in a distribution center environment. Direct ownership of Distribution Center P&L, accountable for $230M in inventory, $50M of Transportation Spend, $2M in labor, and $2M external public warehousing spend.
- Key member of the Global Logistics leadership team, actively participates in the development of the annual work plan and ensures that department activities are in place to deliver results consistent with the plan. Coordinates activities with other departments, customers and suppliers for alignment or resources and approach.
- Developed and supported a culture that promotes waste reduction, troubleshooting and problem solving at the front line level through implementation of Continuous Improvement/LEAN projects and tools.
- Engage with Commercial and New Product Launch teams to ensure that product supply timelines and objectives are clearly understood and that appropriate action plans are developed and implemented to successfully support commercial objectives.

**Director of Warehouse and Transportation** October 2017 - May 2020
Skjodt-Barrett Foods LLC Lebanon, IN

*Skjodt-Barrett Foods Inc. is a leading manufacturer of organic, non-organic, natural and specialty food products.*

- Lead a Supply Chain function of 100 employees throughout the US and Canada. Direct ownership of Warehouse P&L, accountable for $30M in inventory, $5M of Transportation Spend, $4M in labor, and $2M external public warehousing spend.
- Implemented Global Warehouse Capacity Tracking and Forecasting which lead to the improvement of working conditions for site employees and overall plant safety.
- Implemented Warehouse Asset Tracking and Maintenance schedule to include total life cycle cost management which led to proper spend management profile and subsequent change in MHE procurement practices.
- Implemented Warehouse Cycle Counting Program that resulted in two plants achieving 100% inventory accuracy on back to back annual audits.
- Implemented Inventory Management Process that tracked days on hand, expiring, and obsolete material which led to improved capacity utilization, loss reduction and cost recovery, and improved cash flow.

**Supply Chain Manager** October 2016-October 2017
Skjodt-Barrett Foods LLC Lebanon, IN

*Skjodt-Barrett Foods Inc. is a leading manufacturer of organic, non-organic, natural and specialty food products.*

- Led a Department of 50 employees covering Warehouse, Inventory, Customer Service, Planning and Procurement Operations.
- Optimized procurement practices to reduce inventory by 30 days in the first 6 months.
- Drove improvements to customer service by streamlining weekly reporting functions.
- Improved plant schedule attainment performance by driving key improvements in downtime reporting, root cause analysis, capacity planning, and product availability.
- Led two Process Mapping Projects that identified several key gapped processes which led to reduced product waste, improved production efficiency, and increase visibility to product safety.

**Senior Purchasing Agent** April 2014-October 2016
Delta Faucet Company Indianapolis, IN

*Delta Faucet is one of the world's leading manufacturers of branded kitchen faucets and bathroom faucets, and sells these products in 53 countries worldwide.*

- Tasked with developing and implementing an international Supplier Strategy for five commodities, 76 suppliers, 1,400 part numbers as part of a $30 million spend.
- Kept the #1 sourcing project on schedule despite the time frame being moved up by two years.
- Oversee supplier performance, pricing, and effect of commodity market changes, investigate new supply chain options, work cross-functionally on new product development, and collaborate with quality, engineering, marketing, and finance to maximize company goals while minimizing internal conflict.
- Initiate RFQ's for new product projects, or engineering projects and award business per established policy.

Additional Relevant Experience:

UNITED STATES NAVY RESERVE – Secret Clearance/TSI Eligible 2000-Present

**Lead Logistician / MPP 513 US NAVY 6th FLEET** Dec 2016 -Nov 2019
Exercise Sea Breeze Ukraine

- Lead Logistics and Military Contract Representative for multicountry Naval and Land Component military exercise in Odesa Ukraine. Lead a team of 15 personnel covering 6 land and sea-based sites providing key Supply Readiness and Logistics support.
- Led all phases of requirements gathering during the exercise planning phase which resulted in the successful contracting of $12 M in fuel, food, water, and misc contracted base support.

**Support Operations Officer / Executive Officer, Task Force Three** Feb 2013-Dec 2013
United States Navy, *Recall to active Duty – Operation Enduring Freedom* Bagram, Afghanistan

- Led a team of 75 personnel covering 12 Divisions across three countries providing support to the nation's premier Special Operations Joint Task Force; executed 14 key Task Force logistical movements, 30 task Force personnel movements and 60 Customers and Cargo Transportation missions.
- Selected, hired and trained all 75 Sailors including five managers, developed the Organizational Mission Statement, and executed all missions.

**Battalion Executive – Operations Division** Oct 2011-Feb 2013
United States Navy Reserves Indianapolis, IN

- Direct management of 9 junior managers and 12 line managers to an overall passing grade of 88% (normal is 75%) in certifying my unit for forward mobilization missions.
- Crafted a four-month long training program providing key Command and Control training for the Logistics Operation Center and key mission Operations Centers.

**Manager – Surface Cargo Operations** Nov 2009-Oct 2011
United States Navy Reserves Indianapolis, IN

- Managed the development and implementation of Navy-wide quality and productivity improvement initiatives.
- Managed the development of 40 employees across two divisions, and increased operational readiness by 40%.

## EDUCATION AND TRAINING

**MBA, Accounting and Finance** 2011
DEVRY KELLER GRADUATE SCHOOL OF MANAGEMENT Indianapolis, IN

**Bachelor of Science in Accounting** 2000
INDIANA STATE UNIVERSITY Terre Haute, IN

## PROFESSIONAL CERTIFICATIONS

Certified Public Accountant, Indiana
Certified Professional in Supply Management – *Institute for Supply Management*
Defense Contracting Officer Representative – *Defense Acquisition Workforce Improvement Act, 2013*

## Apotex Employee List

Serafin Arada
Robert Baker
Angela Bass-Perez
Abdul Buat
Favian Carlos
Lisa Davenport
Jamie Ehrreich
Luis Flores
Allison Hammack
Cecilia Hern
Maria Hurtado-Soto
Koree Jennings
Wendell Johnson
Brian Lewis
Nahir Linares
Ma Adoracion Marvel
Adam McGill
Samuel Michael
Cassandra Mowery
Edward Ocampo
Amanda Palmer
Floyd Peele
James Releford
Jaime Rodriguez
Vidal Rodriguez
Jeremy Rollins
Kyle Ruschhaupt
Sameem Shaikh
Christina Smith
Marlon Smith
Amanda Stephenson
Aston Suriyothai
Blessie Suriyothai
Mike Workman
Tolulope Akintokun
Waseem Baig
Kristine Heald
Gerardo Hernandez
Margaret Howard
Maria Moreno
Darius Raysor
Tim Trump
Cheryl Vredeveld
Jon Walker
Vladimir Altidor
David Baker

Jerel Chambers
Daniel Coleman
Abigail Fernandez
Christian Fletcher
Morris Hansbrough
Mahamat Ibrahim
James McCullough
Sunday Omoniyi
Abiodun Bakare Onanuga
Rylen Richardson
Brian Sabo

Canada Revenue Agency | Agence du revenu du Canada

OTTAWA ON K1A 1A2

001316

**Date** Sep 22, 2022

**Business number** 70177 4606

ARTEMIS PARENT, INC.
181 BAY STREET
SUITE 4400
TORONTO ON M5J 2T3

Subject: Letter to new registrants

As you requested, we opened a business number or Canada Revenue Agency (CRA) account number for you. You can see the number on the attached Business Number Summary of Accounts.

The summary shows details about your CRA program accounts based on the information you gave us. If you find any errors or omissions, please make changes on the summary and return it to us in the envelope provided.

We may contact you to confirm the information you gave us. Having complete and valid information on file for your business helps us serve you better.

Revenu Québec administers the goods and services tax (GST) for the CRA for businesses in Quebec. If your business is in Quebec and you need a GST account number, contact Revenu Québec toll free at **1-800-567-4692**.

The CRA administers the GST/HST and the QST for listed financial institutions that are selected listed financial institutions (SLFIs) for GST/HST or Quebec sales tax (QST) purposes or both, whether or not the physical location of the business is in Quebec. If you are an SLFI and you need a GST/HST and QST or GST/HST account number, contact CRA toll free at **1-800-959-5525**.

If you have any questions, need publications, or need more CRA account numbers, call the number shown above or go to **canada.ca/revenue-agency**.

We also offer free seminars for small businesses. For a list of current seminars, go to **canada.ca/cra-videos**. You can find import/export information or register for free information sessions at **cbsa-asfc.gc.ca/sme-pme**.

Did you know that **My Business Account** lets you manage tax-related information for your business? Try it and see the difference! Go to **canada.ca/my-cra-business-account** to register.

Thank you,

Bob Hamilton
Commissioner of Revenue



Canada

RC274 E (19)X

# SHARE PURCHASE AGREEMENT

THIS SHARE PURCHASE AGREEMENT is made as of April 1, 2023 (the "**Closing Date**") between

**ARTEMIS PARENT, INC.,**
a corporation existing under the laws of Ontario
(the "**Vendor**")

and

**ARTEMIS INTERMEDIATE HOLDINGS, INC.,**
a corporation existing under the laws of Ontario
(the "**Purchaser**")

**RECITALS:**

A. The Vendor is the registered owner of the Purchased Shares.

B. The Vendor wishes to sell and the Purchaser wishes to acquire the Purchased Shares in consideration for the issuance to the Vendor of the Consideration Shares.

C. The Vendor and the Purchaser wish to elect under subsection 85(1) of the Act in respect of the Purchased Shares.

**FOR VALUE RECEIVED**, the parties agree as follows:

## ARTICLE 1 – INTERPRETATION

### 1.1 Definitions

In this Agreement:

(a) ***Act*** means the Income Tax Act (Canada) and all terms defined in the Act have the same meaning where used in this Agreement.

(b) ***Agreement*** means this share purchase agreement, as amended, supplemented or restated from time to time.

(c) ***Business Day*** has the meaning given to it in Section 5.1.

(d) ***Consideration Shares*** means [redacted] Class A Common shares in the capital of the Purchaser.

(e) ***Corporation*** means Artemis Bidco, Inc.

(f) ***Purchase Price*** has the meaning given to it in Section 2.2.

(g) ***Purchase Price Adjustment*** has the meaning given to it in Section 2.3.

(h) ***Purchased Shares*** means [redacted] Class A Common shares in the capital of the Corporation, being all of the issued and outstanding shares in the capital of the Corporation.

(i) ***Purchaser*** has the meaning given to it in the preamble.

(j) ***Vendor*** has the meaning given to it in the preamble.

## ARTICLE 2 – PURCHASE AND SALE OF PURCHASED SHARES

### 2.1 Purchased Shares

Subject to the terms and conditions of this Agreement, the Vendor agrees to sell and the Purchaser agrees to purchase the Purchased Shares, subject to the Purchase Price Adjustment (as defined below), payable as provided in Section 2.2.

### 2.2 Purchase Price & Payment

The purchase price for the Purchased Shares is the fair market value of such shares on the date hereof (the "**Purchase Price**"), which the parties agree is [redacted]. The Purchaser shall satisfy the Purchase Price for the Purchased Shares by issuing the Consideration Shares to the Vendor as fully paid and non-assessable on the date hereof.

### 2.3 Purchase Price Adjustment

If, at any time in the future, the parties make a determination or any taxing authority or any court of competent jurisdiction makes a determination (to which the parties acquiesce or from which there is no further right to object or appeal) that the fair market value of the Purchased Shares on the date hereof is an amount other than the Purchase Price, the parties agree to adjust the Purchase Price for the Purchased Shares to the fair market value as finally determined, and make such other adjustments as are considered necessary or advisable to give full effect to such Purchase Price adjustment (the "**Purchase Price Adjustment**").

## ARTICLE 3 – TAX ELECTION

The Vendor and the Purchaser shall jointly execute and the Vendor shall file, within the time referred to in subsection 85(6) of the Act, an election in prescribed form under subsection 85(1) of the Act electing to transfer the Purchased Shares for the purposes of the Act at an agreed amount equal to the lesser of: (a) the fair market value of the Purchased Shares on the date hereof, and (b) the Vendor's adjusted cost base of the Purchased Shares immediately before the disposition contemplated by this Agreement and such additional amount as may be determined by the Vendor.

## ARTICLE 4 – REPRESENTATIONS AND WARRANTIES

### 4.1 Representations and Warranties of the Vendor

The Vendor represents and warrants to the Purchaser as follows and acknowledges that the Purchaser is relying on such representations and warranties in connection with its purchase of the Purchased Shares:

(a) the Vendor is the sole legal and beneficial owner of the Purchased Shares free and clear of all liens, charges, encumbrances, security interests and any other rights of others, including, without limitation, any right, option or agreement, whether written or oral, of any person to purchase the Purchased Shares;

(b) the Vendor is valid and subsisting corporation under the laws of Ontario and has the corporate power and authority to enter into and perform its obligations pursuant to this Agreement and to sell the Purchased Shares to the Purchaser;

(c) this Agreement has been duly authorized, executed and delivered by the Vendor and is a valid, binding and enforceable obligation of the Vendor, enforceable against the Vendor by the Purchaser in accordance with its terms;

(d) the Vendor has the exclusive right to dispose of the Purchased Shares as provided in this Agreement;

(e) the Purchased Shares are not subject to the terms of any shareholders' agreement, voting trust, pooling agreement or other agreement;

(f) the execution, delivery and performance by the Vendor of its obligations hereunder and the consummation of the transactions contemplated hereby will not violate, conflict with or result in the breach of (i) any statute, law or regulation applicable to the Vendor or (ii) any agreement to which the Vendor is a party; and

(g) the Vendor is not a non-resident of Canada for the purposes of the Act.

**4.2 Representations and Warranties of the Purchaser**

The Purchaser represents and warrants to the Vendor as follows and acknowledges and confirms that the Vendor is relying on such representations and warranties in connection with the sale by the Vendor of the Purchased Shares:

(a) the Purchaser is a valid and subsisting corporation under the laws of Ontario and has the corporate power and authority to enter into and perform its obligations pursuant to this Agreement;

(b) the Agreement has been duly authorized, executed and delivered by the Purchaser and is a valid, binding and enforceable obligation of the Purchaser, enforceable against the Purchaser by the Vendor in accordance with its terms;

(c) the execution, delivery and performance by the Purchaser of its obligations hereunder and the consummation of the transactions contemplated hereby will not violate, conflict with or result in the breach of (i) any provision of the constating documents of the Purchaser, (ii) any statute, law or regulation applicable to the Purchaser or (iii) any agreement to which the Purchaser is a party; and

(d) the Consideration Shares shall be validly issued and fully paid.

## ARTICLE 5 – GENERAL

### 5.1 Notices

Unless otherwise specified, each notice to a party shall be given in writing and delivered personally or by courier, sent by prepaid registered mail or e-mail or other electronic transmission to the applicable address, e-mail or person that the party designates and as may be updated from time to time. Any notice, if delivered: (a) personally or by courier, will be deemed to have been given and received on the day it is so delivered and at such address; (b) by pre-paid registered mail, will be deemed to have been given and received on the fourth day following the date of its mailing, provided that such day is any day except Saturday, Sunday or any statutory holiday in the Province of Ontario (a "**Business Day**"); or (c) by e-mail or other electronic transmission, will be deemed to have been given and received at the time of dispatch if sent or delivered on a Business Day or, if not sent or delivered on a Business Day, on the next following Business Day.

### 5.2 Survival

All representations and warranties contained in this Agreement shall survive this Agreement and the consummation of the transactions contemplated by it.

### 5.3 Currency

All dollar amounts referred to in this Agreement are stated in Canadian Dollars.

### 5.4 Further Assurances

The Vendor and the Purchaser hereby covenant and agree that at any time and from time to time after the Closing Date each of them will, upon reasonable request of the other party, do, execute, acknowledge and deliver or cause to be done, executed, acknowledged and delivered all such further acts, deeds, assignments, transfers, conveyances, powers of attorney and assurances as may reasonably be required for the better carrying out and performance of all the terms of this Agreement.

### 5.5 Entire Agreement

This Agreement, and all agreements, contracts, instruments, certificates or other documents to be executed or delivered pursuant to this Agreement, constitute the entire Agreement between the parties pertaining to the subject matter hereof and supersede any prior agreements between the parties hereto.

### 5.6 Governing Law

This Agreement is governed by, and is to be construed and interpreted in accordance with, the laws of the Province of Ontario and the laws of Canada applicable therein.

### 5.7 Binding Effect and Assignment

This Agreement shall enure to the benefit of and be binding upon the parties hereto and their respective heirs, executors, administrators, personal and legal representatives, successors and

permitted assigns. Neither party may assign this Agreement or any part hereof without the prior written consent of the other party.

**5.8 Severability**

If any provision of this Agreement is or becomes illegal, invalid or unenforceable in any jurisdiction, the illegality, invalidity or unenforceability of that provision will not affect:

(a) the legality, validity or enforceability of the remaining provisions of this Agreement; or

(b) the legality, validity or enforceability of that provision in any other jurisdiction.

**5.9 Waivers**

No waiver of any provision of this Agreement is binding unless it is in writing and signed by all the parties to this Agreement entitled to grant the waiver. No failure to exercise, and no delay in exercising, any right or remedy, under this Agreement will be deemed to be a waiver of that right or remedy. No waiver of any breach of any provision of this Agreement will be deemed to be a waiver of any subsequent breach of that provision.

**5.10 Time of Essence**

For every provision of this Agreement, time is of the essence.

**5.11 Headings**

The division of this Agreement into Sections and the insertion of headings are for convenient reference only and do not affect the construction or interpretation of this Agreement.

**5.12 Counterpart and Electronic Signatures**

This Agreement and any other documents to be delivered pursuant to this Agreement may be executed and delivered in (a) any number of counterparts, each of which when executed and delivered is an original but all of which taken together constitute one and the same instrument, and (b) either paper form or in digital form by electronic transmission in PDF format or by way of an electronic signature platform. Any such digital execution and delivery shall constitute effective execution and delivery of this Agreement and such other documents.

*[Signature page follows]*

The parties have executed this Agreement as of the Closing Date.

**ARTEMIS PARENT, INC.**

Per: 

Name: Aaron Davenport
Title: President

**ARTEMIS INTERMEDIATE HOLDINGS, INC.**

Per: 

Name: Aaron Davenport
Title: President

Canada Revenue Agency | Agence du revenu du Canada

# Business Number Summary Of Accounts

Protected B when completed

001317



Business number
70177 4606

BUSINESS NUMBER
CANADA REVENUE AGENCY
PO Box 20000 Stn A
Sudbury ON P3A 5C1

Toll-free in Canada
1-800-959-5525

Facsimile number
1-705-671-0490

## Business identification

Name
ARTEMIS PARENT, INC.

Operating or trading name(s)
NOT PROVIDED

## Legal entity information

**Business address**
181 BAY STREET
SUITE 4400
TORONTO ON M5J 2T3

**Mailing address**
181 BAY STREET
SUITE 4400
TORONTO ON M5J 2T3

**Legal status**
CORPORATION

**Language**
ENGLISH

Corporation information
Incorporation certicate number
1000314038

Incorporation date
2022-09-16

## Owner / partner / director information

Name
Aaron
DAVENPORT

| Work telephone number | Work fax number | Home telephone number | Home fax number |
|---|---|---|---|
| NOT PROVIDED | NOT PROVIDED | NOT PROVIDED | NOT PROVIDED |

Name
Jerry
TRUZZOLINO

| Work telephone number | Work fax number | Home telephone number | Home fax number |
|---|---|---|---|
| NOT PROVIDED | NOT PROVIDED | NOT PROVIDED | NOT PROVIDED |

Name
Jayesh
TAUNK

| Work telephone number | Work fax number | Home telephone number | Home fax number |
|---|---|---|---|
| NOT PROVIDED | NOT PROVIDED | NOT PROVIDED | NOT PROVIDED |



Canada

Business number
70177 4606

Name
ARTEMIS PARENT, INC.

# Business Number Summary Of Accounts



## Summary of accounts

**Account number**
70177 4606 RC0001

**Effective date**
2022-09-16

**Account type**
CORPORATION INCOME TAX

**Account name**
NOT PROVIDED

**Mailing address**
181 BAY STREET
SUITE 4400
TORONTO ON M5J 2T3

**Language**
ENGLISH

## Major business activity

**Description of major business activity**
HOLDING THE SECURITIES OF OTHER BUSINESSES, FOR THE PURPOSE OF EXERCISING CONTROL (SEE 551113 HOLDING COMPANIES (CAN))

| Main products or services | Percentage of revenue |
|---|---|

Personal information is collected under the Income Tax Act, Excise Tax Act, and other legislation to administer tax, benefits, rebates, elections, and related programs. It may also be used for any purpose related to the administration or enforcement of these Acts such as audit, compliance and the payment of debts owed to the Crown. It may be shared or verified with other federal, provincial/territorial government institutions to the extent authorized by law. Failure to provide this information may result in interest payable, penalties or other actions. Under the Privacy Act, individuals have the right to access their personal information and request correction if there are errors or omissions. Refer to Info Source at cra.gc.ca/gncy/tp/nfsrc/nfsrc-eng.html, personal information bank CRA PPU 223.

# INSTRUMENT OF TRANSFER

FOR VALUE RECEIVED, the undersigned sells, assigns and transfers to Artemis Parent, Inc. 165,040 common shares in the capital of Apotex Pharmaceutical Holdings Inc. (the "**Corporation**"), representing all of the shares in the capital of the Corporation registered in the name of the undersigned on the securities register of the Corporation.

DATED as of April 1, 2023.

**SHERFAM INC.**

by Jonathan Grauman
Name: Jonathan Grauman
Title: Vice-President

Canada Revenue Agency | Agence du revenu du Canada

OTTAWA ON K1A 1A2

001300

**Date** Sep 22, 2022

**Business number** 70177 0802

ARTEMIS INTERMEDIATE HOLDINGS,
181 BAY STREET
SUITE 4400
TORONTO ON M5J 2T3

Subject: Letter to new registrants

As you requested, we opened a business number or Canada Revenue Agency (CRA) account number for you. You can see the number on the attached Business Number Summary of Accounts.

The summary shows details about your CRA program accounts based on the information you gave us. If you find any errors or omissions, please make changes on the summary and return it to us in the envelope provided.

We may contact you to confirm the information you gave us. Having complete and valid information on file for your business helps us serve you better.

Revenu Québec administers the goods and services tax (GST) for the CRA for businesses in Quebec. If your business is in Quebec and you need a GST account number, contact Revenu Québec toll free at **1-800-567-4692**.

The CRA administers the GST/HST and the QST for listed financial institutions that are selected listed financial institutions (SLFIs) for GST/HST or Quebec sales tax (QST) purposes or both, whether or not the physical location of the business is in Quebec. If you are an SLFI and you need a GST/HST and QST or GST/HST account number, contact CRA toll free at **1-800-959-5525**.

If you have any questions, need publications, or need more CRA account numbers, call the number shown above or go to **canada.ca/revenue-agency**.

We also offer free seminars for small businesses. For a list of current seminars, go to **canada.ca/cra-videos**. You can find import/export information or register for free information sessions at **cbsa-asfc.gc.ca/sme-pme**.

Did you know that **My Business Account** lets you manage tax-related information for your business? Try it and see the difference! Go to **canada.ca/my-cra-business-account** to register.

Thank you,

Bob Hamilton
Commissioner of Revenue



Canada

Canada Revenue Agency | Agence du revenu du Canada

# Business Number Summary Of Accounts

Protected B when completed

001301



Business number
70177 0802

BUSINESS NUMBER
CANADA REVENUE AGENCY
PO Box 20000 Stn A
Sudbury ON P3A 5C1

Toll-free in Canada
1-800-959-5525

Facsimile number
1-705-671-0490

## Business identification

Name
ARTEMIS INTERMEDIATE HOLDINGS, INC.

Operating or trading name(s)
NOT PROVIDED

## Legal entity information

**Business address**
181 BAY STREET
SUITE 4400
TORONTO ON M5J 2T3

**Mailing address**
181 BAY STREET
SUITE 4400
TORONTO ON M5J 2T3

**Legal status**
CORPORATION

**Language**
ENGLISH

Corporation information
Incorporation certicate number
1000314009

Incorporation date
2022-09-16

## Owner / partner / director information

Name
Aaron
DAVENPORT

| Work telephone number | Work fax number | Home telephone number | Home fax number |
|---|---|---|---|
| NOT PROVIDED | NOT PROVIDED | NOT PROVIDED | NOT PROVIDED |

Name
Jerry
TRUZZOLINO

| Work telephone number | Work fax number | Home telephone number | Home fax number |
|---|---|---|---|
| NOT PROVIDED | NOT PROVIDED | NOT PROVIDED | NOT PROVIDED |

Name
Jayesh
TAUNK

| Work telephone number | Work fax number | Home telephone number | Home fax number |
|---|---|---|---|
| NOT PROVIDED | NOT PROVIDED | NOT PROVIDED | NOT PROVIDED |



Canada

Business number
70177 0802

# Business Number Summary Of Accounts

Name
ARTEMIS INTERMEDIATE HOLDINGS, INC.



## Summary of accounts

**Account number**
70177 0802 RC0001

**Effective date**
2022-09-16

**Account type**
CORPORATION INCOME TAX

**Account name**
NOT PROVIDED

**Mailing address**
181 BAY STREET
SUITE 4400
TORONTO ON M5J 2T3

**Language**
ENGLISH

## Major business activity

**Description of major business activity**
HOLDING THE SECURITIES OF OTHER BUSINESSES, FOR THE PURPOSE OF EXERCISING CONTROL (SEE 551113 HOLDING COMPANIES (CAN))

| Main products or services | Percentage of revenue |
|---|---|

Personal information is collected under the Income Tax Act, Excise Tax Act, and other legislation to administer tax, benefits, rebates, elections, and related programs. It may also be used for any purpose related to the administration or enforcement of these Acts such as audit, compliance and the payment of debts owed to the Crown. It may be shared or verified with other federal, provincial/territorial government institutions to the extent authorized by law. Failure to provide this information may result in interest payable, penalties or other actions. Under the Privacy Act, individuals have the right to access their personal information and request correction if there are errors or omissions. Refer to Info Source at **cra.gc.ca/gncy/tp/nfsrc/nfsrc-eng.html**, personal information bank **CRA PPU 223**.

# 4BB

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

**Non-Refundable $1,000 Fee**

Rev (08/17/2022)

| **Where is the facility located?** | | ☐ Nevada ☒ Out-of-State |
|---|---|---|
| **Type of Application (check applicable box)** | | **Wholesaler Business Type (check applicable box)** |
| ☐ New Wholesaler<br>☒ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH 02318 | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☒ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: AstraZeneca Pharmaceuticals LP

Physical Address: 355 Omicron Court

City: Shepherdsville State: KY Zip: 40165

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 502-543-5102 Website: www.astrazeneca-us.com

Name of Designated Representative (DR): Chad Hack

Licensing Company Email: usdruglicensing@astrazeneca.com DR Email: chad.hack@astrazeneca.com

| **Entities the Wholesaler will Serve (✓ all applicable)** | **Products to be Handled or Wholesaled (✓ all applicable)** | **Type of Wholesaling (✓ all applicable)** |
|---|---|---|
| ☒ Pharmacies | ☐ Dangerous Drugs | ☐ Manufacturer |
| ☒ Practitioners | ☐ Controlled Substances | ☐ Repacker |
| ☒ Hospitals | ☐ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ☒ Wholesalers | ☒ Others: FluMist Influenza Vaccine Live Intranasal | ☐ Warehouse |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ☐ Others: | | ☒ Others: Wholesaler Storage and Distributor |

| **Section 2: History of Company** | **Yes** | **No** |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | x |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | x |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | x |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | x |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | x |

*Note: The applicant site only receives AZ owned manufactured products from the site below located at 3001 Red Lion Road, Philadelphia, PA 19114.*

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: AstraZeneca Pharmaceuticals LP
Address: 3001 Red Lion Rd City: Philadelphia State: PA Zip: 19114
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

**Section 4: Publicly Traded Corporation**

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation**

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

**Section 6: Partnership**

Partnership Name: AstraZeneca Pharmaceuticals LP
Mailing Address: 355 Omicron Court
City: Shepherdsville State: KY Zip: 40165
Telephone: 502-612-2250 Email: usdruglicensing@astrazeneca.com
Contact Person Name: Shannon Grimes

**Section 7: Sole Owner**

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

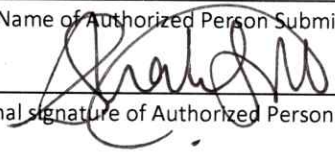
| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | ✓ | |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | ✓ | |
| 1. Copy of FDA registration<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |

| Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** | | ✓ | | |
| • **List of all partners and their percent ownership.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**. | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Form is found at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Form is found at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) | ✓ | | | |
| • **A list containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered.** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Shah Maliha

Print Name of Authorized Person Submitting Application



Original signature of Authorized Person (copies or stamps not accepted)

06/05/2023

Date

| Board Use Only | Date Received: 6/27/23 | Amount: 1000-CC |
|---|---|---|

AstraZeneca

AstraZeneca Pharmaceuticals LP
355 Omicron Court
Shepherdsville, KY 40165

Astrazeneca-us.com

June 20th, 2023

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

Reference number: Change of Ownership/List of Partners and Percent Ownership
AstraZeneca Pharmaceuticals LP

355 Omicron Court
Shepherdsville, KY 40165

To Whom It May Concern:

A change of ownership has occurred at AstraZeneca Pharmaceuticals LP due to a legal entity integration transaction. There is no change to the address, ownership name and EIN. The only change is the actual owners. The parent company remains the same.

According to Nevada's rules and regulations, we are required "to apply for new applications. Any change of ownership and/or location change, will require a new application and $1000.00 fee."

The current license we hold with Nevada is listed below.

| State | Type of License Issued | License No. | Expiration Date |
|---|---|---|---|
| Nevada | Wholesaler Registration | WH02318 | 10/31/2024 |

**AstraZeneca Pharmaceuticals LP Ownership Information**

Current Ownership

**Zeneca Inc**
1800 Concord Pike, Wilmington, DE 19807
(FEIN) 51-0012320
19.989%

**AstraZeneca AB**
SE-151 85 Sodertalje, Sweden
(EIN) 98-0192371
34.892%

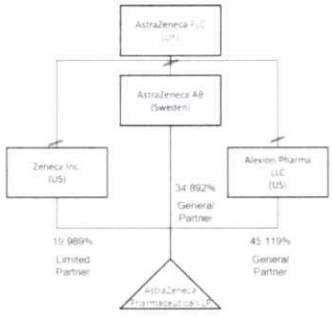
**Alexion Pharma LLC**
100 College Street, New Haven, CT 06510
(FEIN) 47-4379225
45.119%

# AstraZeneca Group

## Extract of legal entity structure as of 31 December 2022

AstraZeneca Pharmaceuticals LP
355 Omicron Court
Shepherdsville, KY 40165

Astrazeneca-us.com




**Point of Contact**

Shannon Grimes
phone: 502-612-2250
e-mail: shannon.grimes1@astrazeneca.com

**Mailing Address**

AstraZeneca Pharmaceuticals LP
Attn: Shannon Grimes
355 Omicron Court
Shepherdsville, KY 40165

Kind regards,

Shah Maliha
Drug Licensing Manager
AstraZeneca Pharmaceuticals LP
phone: 267-279-6889
e-mail: shah.maliha1@astrazeneca.com

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/18/2023)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: AstraZeneca Pharmaceuticals LP

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): WH-02318

Physical Address: 355 Omicron Court

City: Shepherdsville State: KY Zip: 40165

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 502-543-5102 Website: www.astrazeneca-us.com

Licensing Company Email: usdruglicensing@astrazeneca.com

**Section 2: Personal Information**

First: Shah Middle: S Last: Maliha

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: 355 Omicron Court

City: Shepherdsville State: KY Zip: 40165

Telephone: [redacted] Email: shah.maliha1@astrazeneca.com

Are you a citizen of the United States? ☒ Yes ☐ No

| **Section 3: Military Service (NRS 622.120)** | **Yes** | **No** |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| **Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)** | **Yes** | **No** |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Temple University | | | 08/2018-05/2023 | |
| Address | | City | State | Zip |
| 1801 N Broad Street | | Philadelphia | PA | 19122 |
| Diploma/Degree obtained, if any | | | | |
| Business Administration | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| North Penn High School | | | 09/10-06/13 | |
| Address | | City | State | Zip |
| 840 S Valley Forge Rd | | Lansdale | PA | 19446 |
| Diploma/Degree obtained, if any | | | | |
| High School Diploma | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |
| School Name | | | From - To (MM/YY – MM/YY | |
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 07/23-Current | [redacted] Collins Street | Philadelphia | PA | 19125 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| 08/22-07/23 | [redacted] Ridge Ave | Philadelphia | PA | 19128 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| 07/11-08/22 | [redacted] Woodlawn Drive | Lansdale | PA | 19446 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| AstraZeneca Pharmaceuticals LP | | | 04/23-Current |
| **Business Address** | **City** | **State** | **Zip** |
| 1800 Concord Pike | Wilmington | DE | 19850 |
| **Phone** | **Title** | | |
| 1-800-456-3669 | Drug Licensing Manager | | |

Description of Duties

CMC Drug Licensing Manager is accountable for all AstraZeneca Drug Registration and Listing activities, as well as all State and Federal licenses. In addition to creating and managing National Drug Codes for all products.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Merck & Co. / HCL | | | 02/2021-04/2022 |
| **Business Address** | **City** | **State** | **Zip** |
| 351 N. Sumneytown Pike | North Wales | PA | 19454 |
| **Phone** | **Title** | | |
| 1-800-672-6372 | Regulatory Submissions Manager | | |

Description of Duties

Reviewed promotional materials for the Gardasil-9 product. Submitted files to the FDA for approval. Set up Veeva Vault/ Promomats system for the company by troubleshooting digital submission workflows.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |

Description of Duties

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |

Description of Duties

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |

Description of Duties

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✓ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✓ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✓ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| | | | | |
| Reason/Charge | | | | |
| | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| | | | | |
| Name of Business/Industry/Entity | | | | |
| | | | | |

**Provide explanation below:**

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Shah Maliha

Print Name (First, Last)

Original Signature (electronic copies or stamps not accepted)

06/20/2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of DE, ss. County of New Castle

I, Shah Maliha, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

6/20/23

**Date**

Subscribed and Sworn to before me this 20 day of 2023, June

**Notary Public Signature**

**(Seal)**



SSM

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

# Drug Establishments Current Registration Site

Verified 6.27.23

New Search (default.cfm)

Search Results for **AstraZeneca Pharmaceuticals, LP**

CSVExcel

**Filter:**

| Firm Name | FDA Establishment Identifier | DUNS | Business Operations | Address | Expiration Date |
|---|---|---|---|---|---|
| AstraZeneca Pharmaceuticals, LP | 3014798309 | 190578984 | MANUFACTURE; | 355 Omicron Ct, Shepherdsville, Kentucky (KY) 40165, United States (USA) | 12/31/2023 |

Showing 1 to 1 of 1 entries
Previous1Next
Data Current through: Wednesday, Jun 7, 2023

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

1209

# NABP ACCREDITED
## DRUG DISTRIBUTOR

AstraZeneca Pharmaceuticals LP

located at

355 Omicron Court, Shepherdsville, KY 40165

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

**Lemrey "Al" Carter,** PharmD, MS, RPh
*Executive Director/Secretary*

08/24/2022 - 08/23/2025
Period of Accreditation

| Name | Title | Address | Phone | Email |
|---|---|---|---|---|
| | | | | |
| Andrew Wirths | SVP Supply, Americas | One Medimmune Way Gaithersburg, MD 20878 | 215-534-2004 | andrew.wirths@astrazeneca.com |
| | | | | |
| David E. White | Treasurer | 1800 Concord Pike Wilmington, DE 19850 | 302-886-6994 | david.e.white@astrazeneca.com |
| | | | | |
| Kevin P. Durning | US CFO, VP Finance | 1800 Concord Pike Wilmington, DE 19850 | 610-329-3073 | kevin.durning@astrazeneca.com |

# Commonwealth of Kentucky
## Michael G. Adams, Secretary of State

Michael G. Adams
Secretary of State
P. O. Box 718
Frankfort, KY 40602-0718
(502) 564-3490
http://www.sos.ky.gov

## Certificate of Authorization

Authentication number: 286875
Visit https://web.sos.ky.gov/ftshow/certvalidate.aspx to authenticate this certificate.

I, Michael G. Adams, Secretary of State of the Commonwealth of Kentucky, do hereby certify that according to the records in the Office of the Secretary of State,

**ASTRAZENECA PHARMACEUTICALS LP**
**adopting, in Kentucky, the fictitious name of**
**ASTRAZENECA PHARMACEUTICALS LIMITED PARTNERSHIP**

, a limited partnership authorized under the laws of the state of Delaware, is authorized to transact business in the Commonwealth of Kentucky, and received the authority to transact business in Kentucky on December 2, 1999.

I further certify that all fees and penalties owed to the Secretary of State have been paid; that a certificate of cancellation has not been filed; and that the most recent annual report required by KRS 14A.6-010 has been delivered to the Secretary of State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my Official Seal at Frankfort, Kentucky, this 28th day of February, 2023, in the 231st year of the Commonwealth.

Michael G. Adams
Secretary of State
Commonwealth of Kentucky
286875/0484327

# COMMONWEALTH OF KENTUCKY

## KENTUCKY BOARD OF PHARMACY

State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601

LICENSE/PERMIT: Wholesale Distributor

EFFECTIVE DATE: 12/20/2016

NUMBER: W03830

EXPIRATION DATE: 09/30/2023

Issued to:
ASTRAZENECA PHARMACEUTICALS LP

355 OMICRON COURT
SHEPHERDSVILLE, KY 40165

License/Permit must be posted in public view.

The official status of this license/permit can be verified at www.pharmacy.ky.gov.

The facility above is hereby licensed or permitted at the above address, and is subject to the rules and regulations of the Kentucky Board of Pharmacy.

shannon.grimes1@astrazeneca.com

# VERIFICATION OF BOND IN FORCE
**Form SB-3**

Type of Bond: License/Permit Bond

Name of Principal: ASTRAZENECA PHARMACEUTICALS LP 355 Omicron Court, Shepherdsville, KY 40165

Obligee: THE STATE OF NEVADA AND TO THE NEVADA STATE BOARD OF PHARMACY

Carrier: FIDELITY AND DEPOSIT COMPANY OF MARYLAND

Bond Number: 09232838

Effective Date: March 20, 2023

Limit: $ 100,000.00

Premium: $ 250.00

This Bond is continuous with no definite expiration date. Sufficient Premium has been paid to satisfy the requirements of the Carrier for this bond to March 20, 2024.

FIDELITY AND DEPOSIT COMPANY OF MARYLAND

By: _____
Wayne G. McVaugh Attorney in Fact

Date: June 8, 2023

**ZURICH AMERICAN INSURANCE COMPANY**
**COLONIAL AMERICAN CASUALTY AND SURETY COMPANY**
**FIDELITY AND DEPOSIT COMPANY OF MARYLAND**
**POWER OF ATTORNEY**

KNOW ALL MEN BY THESE PRESENTS: That the ZURICH AMERICAN INSURANCE COMPANY, a corporation of the State of New York, the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, a corporation of the State of Illinois, and the FIDELITY AND DEPOSIT COMPANY OF MARYLAND a corporation of the State of Illinois (herein collectively called the "Companies"), by Robert D. Murray, Vice President, in pursuance of authority granted by Article V, Section 8, of the By-Laws of said Companies, which are set forth on the reverse side hereof and are hereby certified to be in full force and effect on the date hereof, do hereby nominate, constitute, and appoint AnnMarie BREENE, Joanne C. WAGNER, Patricia DORSANEO, Cathy H. HO, Patricia A. RAMBO, Sara OWENS, Kimberly G. SHERROD, George GIONIS, Babette WARD, Dana DONAHUE, Lori S. SHELTON, Wayne G. MCVAUGH, **all of Philadelphia, Pennsylvania,** its true and lawful agent and Attorney-in-Fact, to make, execute, seal and deliver, for, and on its behalf as surety, and as its act and deed: **any and all bonds and undertakings,** and the execution of such bonds or undertakings in pursuance of these presents, shall be as binding upon said Companies, as fully and amply, to all intents and purposes, as if they had been duly executed and acknowledged by the regularly elected officers of the ZURICH AMERICAN INSURANCE COMPANY at its office in New York, New York., the regularly elected officers of the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY at its office in Owings Mills, Maryland., and the regularly elected officers of the FIDELITY AND DEPOSIT COMPANY OF MARYLAND at its office in Owings Mills, Maryland., in their own proper persons.

The said Vice President does hereby certify that the extract set forth on the reverse side hereof is a true copy of Article V, Section 8, of the By-Laws of said Companies, and is now in force.

IN WITNESS WHEREOF, the said Vice-President has hereunto subscribed his/her names and affixed the Corporate Seals of the said **ZURICH AMERICAN INSURANCE COMPANY, COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, and FIDELITY AND DEPOSIT COMPANY OF MARYLAND,** this 21st day of March, A.D. 2023.

**ATTEST:**
**ZURICH AMERICAN INSURANCE COMPANY**
**COLONIAL AMERICAN CASUALTY AND SURETY COMPANY**
**FIDELITY AND DEPOSIT COMPANY OF MARYLAND**

*By: Robert D. Murray*
*Vice President*

*By: Dawn E. Brown*
*Secretary*

**State of Maryland**
**County of Baltimore**

On this 21st day of March, A.D. 2023, before the subscriber, a Notary Public of the State of Maryland, duly commissioned and qualified, **Robert D. Murray, Vice President and Dawn E. Brown, Secretary** of the Companies, to me personally known to be the individuals and officers described in and who executed the preceding instrument, and acknowledged the execution of same, and being by me duly sworn, deposeth and saith, that he/she is the said officer of the Company aforesaid, and that the seals affixed to the preceding instrument are the Corporate Seals of said Companies, and that the said Corporate Seals and the signature as such officer were duly affixed and subscribed to the said instrument by the authority and direction of the said Corporations.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal the day and year first above written.

Iva Bethea
Notary Public
My Commission Expires September 30, 2023

**Authenticity of this bond can be confirmed at bondvalidator.zurichna.com or 410-559-8790**

## EXTRACT FROM BY-LAWS OF THE COMPANIES

"Article V, Section 8, Attorneys-in-Fact. The Chief Executive Officer, the President, or any Executive Vice President or Vice President may, by written instrument under the attested corporate seal, appoint attorneys-in-fact with authority to execute bonds, policies, recognizances, stipulations, undertakings, or other like instruments on behalf of the Company, and may authorize any officer or any such attorney-in-fact to affix the corporate seal thereto; and may with or without cause modify of revoke any such appointment or authority at any time."

## CERTIFICATE

I, the undersigned, Vice President of the ZURICH AMERICAN INSURANCE COMPANY, the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY, and the FIDELITY AND DEPOSIT COMPANY OF MARYLAND, do hereby certify that the foregoing Power of Attorney is still in full force and effect on the date of this certificate; and I do further certify that Article V, Section 8, of the By-Laws of the Companies is still in force.

This Power of Attorney and Certificate may be signed by facsimile under and by authority of the following resolution of the Board of Directors of the ZURICH AMERICAN INSURANCE COMPANY at a meeting duly called and held on the 15th day of December 1998.

RESOLVED: "That the signature of the President or a Vice President and the attesting signature of a Secretary or an Assistant Secretary and the Seal of the Company may be affixed by facsimile on any Power of Attorney...Any such Power or any certificate thereof bearing such facsimile signature and seal shall be valid and binding on the Company."

This Power of Attorney and Certificate may be signed by facsimile under and by authority of the following resolution of the Board of Directors of the COLONIAL AMERICAN CASUALTY AND SURETY COMPANY at a meeting duly called and held on the 5th day of May, 1994, and the following resolution of the Board of Directors of the FIDELITY AND DEPOSIT COMPANY OF MARYLAND at a meeting duly called and held on the 10th day of May, 1990.

RESOLVED: "That the facsimile or mechanically reproduced seal of the company and facsimile or mechanically reproduced signature of any Vice-President, Secretary, or Assistant Secretary of the Company, whether made heretofore or hereafter, wherever appearing upon a certified copy of any power of attorney issued by the Company, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

IN TESTIMONY WHEREOF, I have hereunto subscribed my name and affixed the corporate seals of the said Companies, this 8th day of June, 2023.






By: Mary Jean Pethick
Vice President

**TO REPORT A CLAIM WITH REGARD TO A SURETY BOND, PLEASE SUBMIT A COMPLETE DESCRIPTION OF THE CLAIM INCLUDING THE PRINCIPAL ON THE BOND, THE BOND NUMBER, AND YOUR CONTACT INFORMATION TO:**

Zurich Surety Claims
1299 Zurich Way
Schaumburg, IL 60196-1056
reportsfclaims@zurichna.com
800-626-4577

**Authenticity of this bond can be confirmed at bondvalidator.zurichna.com or 410-559-8790**

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

**Section 1: Pharmacy/Wholesaler Information**

Name of Pharmacy/Wholesaler AstraZeneca Pharmaceuticals LP

Pharmacy/Wholesaler License # (if applicable) WHO2318

Physical Address 355 Omicron Court

City Shepherdsville State KY Zip 40165

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 502-543-5102 Website www.astrazeneca-us.com

Licensing Company Email usdruglicensing@astrazeneca.com

**Section 2: Personal Information**

First Chad Middle _____ Last Hack

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address 355 Omicron Court

City Shepherdsville State KY Zip 40165

Telephone 502-492-8336 Email chad.hack@astrazeneca.com

Are you a citizen of the United States? ■ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | N/A |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | N/A |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Butler Traditional High School | | 09/98-06/02 | |
| Address | City | State | Zip |
| 2222 Crums Ln | Louisville | KY | 40216 |
| Diploma/Degree obtained, if any | | | |
| High School Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| University of Louisville | | 08/02-05/07 | |
| Address | City | State | Zip |
| 2301 S 3rd St | Louisville | KY | 40292 |
| Diploma/Degree obtained, if any | | | |
| Business Administration | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

N/A

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 06/18-Present | [redacted] Running Fox Drive | Shepherdsville | KY | 40165 |
| 06/13-6/18 | [redacted] Watsonville Rd | Louisville | KY | 40216 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

N/A

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| AstraZeneca Pharmaceuticals LP | | | 10/22-Present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 355 Omicron Court | | Shepherdsville | KY | 40165 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 502-543-5102 | Designated Representative | | 1280 | |
| **Description of Duties** | | | | |
| - Involved with all operations on-site.<br>- serve as facility point of contact | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| AstraZeneca Pharmaceuticals LP | | | 04/19-10/22 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 355 Omicron Court | | Shepherdsville | KY | 40165 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 502-543-5102 | Distribution Analyst | | 4960 | |
| **Description of Duties** | | | | |
| -manage the relationships with 3rd party providers and AZ-supply chain partners<br>-coordinate and execute stock replenishments / manage inventory | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

N/A

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

N/A

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✓ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✓ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✓ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

N/A

Original Signature (electronic, copies or stamps not accepted)

07 Jun 2023
Date

I, Chad Hack, **certify that as the designated representative for**

AstraZeneca Pharmaceuticals LP,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. ch I am at least 21 years of age;
3. ch I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ch I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ch I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ch I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ch I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Chad Hack

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07 Jun 2023

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Chad Hack

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07 Jun 2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Kentucky, ss. County of Bullitt

I, Chad Hack, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

07 Jun 2023

**Date**

Subscribed and Sworn to before me this 07 day of June 2023

Shannon Grimes

**Notary Public Signature**

(Seal)

Shannon M. Grimes
Notary Public, ID KYNP26294
State at Large, Kentucky
My Commission Expires on April 2, 2025

# Employee List

| Employees | | |
|---|---|---|
| Name | Position | Agency |
| Melissa Campbell | Purchas./Licensing/Train. Specialist | UPS FTE |
| Jody Wagoner | Training Specialist | UPS FTE |
| Pete Dallas | Maint. Tech. Specialist | UPS FTE |
| Cameron Brussell | Maint. Tech. Specialist | UPS FTE |
| Matt Zimmerman | Transportation Admin. | UPS FTE |
| Jonathan Thompson | Warehouse | UPS FTE |
| Jessica Harris | Warehouse | UPS FTE |
| Penny Webster | Warehouse | UPS FTE |
| Cameron Brussell | Warehouse | UPS FTE |
| Lauren Yaste | Warehouse | UPS FTE |
| Brianna Veach | Warehouse | UPS FTE |
| Daniel Craig | Warehouse | UPS FTE |
| Brianna Weed | Warehouse | UPS FTE |

| UPS Management | | |
|---|---|---|
| Ellen Rhodes | OPS Manager | UPS FTE |
| Hayden Tarpley | Facilities Mgr./Supervisor | UPS FTE |
| April Lyons | SHE Manager/Supervisor | UPS FTE |
| Kenneth Green | Project Manager/Supervisor | Easi Eng. |
| Martha Lincoln | OPS Supervisor | UPS FTE |
| Chandria Johnson | OPS Supervisor | UPS FTE |
| Josh Lomonaco | UPS QA Mgr./Supervisor | UPS FTE |
| | | |
| **AZ Team** | | |
| Chad Hack | Facility Director | AZ |
| Philip Goodloe | QA Manager | AZ |
| Donnetta Peabody | QA Technical Specialist | AZ |
| Eric Hunter | Validation | Contractor |
| Israel Torres* | Validation | Contractor |
| Shannon Grimes* | Drug Licensing Manager Regulatory Affairs | AZ Global |

| Security Team | | |
|---|---|---|
| Linda Moch** | Security Supervisor | Allied |
| Tina Miller** | Security Guard | Allied |
| Darian Giacullo** | Security Guard | Allied |
| Matthew Wilson | Security Guard | Allied |
| Thomas Feger** | Security Guard | Allied |

* May not be on site, works from home periodically

**May not be on site, works different or mulitple shifts

| Agent | | |
|---|---|---|
| Address:<br>C T Corporation System<br>701 South Carson Street Suite 200<br>Carson City, Nevada 89701 | State of Nevada | CT Corporation System |
| | | |
| | | |
| | | |
| | | |

# 4CC

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

**Non-Refundable $1,000 Fee**

Rev (08/17/2022)

| Where is the facility located? | | ☐ Nevada ☒ Out-of-State |
|---|---|---|
| **Type of Application (check applicable box)** | | **Wholesaler Business Type (check applicable box)** |
| ☒ New Wholesaler<br>☐ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH _____ | ☒ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: Aadi Bioscience, Inc.

Physical Address: 17383 Sunset Boulevard, Suite A250

City: Pacific Palisades State: CA Zip: 90272

Mailing Address (if different from physical address): 17383 Sunset Boulevard, Suite A250

City: Pacific Palisades State: CA Zip: 90272

Telephone: 424-744-8055 Website: https://aadibio.com

Name of Designated Representative (DR): John Glennon

Licensing Company Email: statelicensing@aadibio.com DR Email: jglennon@addibio.com

| Entities the Wholesaler will Serve (✓ all applicable) | Products to be Handled or Wholesaled (✓ all applicable) | Type of Wholesaling (✓ all applicable) |
|---|---|---|
| ☒ Pharmacies | ☒ Dangerous Drugs | ☐ Manufacturer |
| ☒ Practitioners | ☐ Controlled Substances | ☐ Repacker |
| ☒ Hospitals | ☐ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ☒ Wholesalers | ☐ Others: | ☐ Warehouse |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ☒ Others: Specialty Pharmacies, Military | | ☒ Others: Virtual Manufacturer |

| Section 2: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | x |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | x |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | x |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | x |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | x |

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: N/A - No Suppliers sold, dispensed or distributed w/i last year

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

**Section 4: Publicly Traded Corporation**

State of Incorporation: DE

Parent Company (if any): N/A

Corporation Name: Aadi Bioscience, Inc.

Mailing Address: 17383 Sunset Boulevard, Suite A250

City: Pacific Palisades State: CA Zip: 90272

Telephone: (424) 744-8055 Email: statelicensing@aadibio.com

Contact Person Name: John Glennon

Date of SEC Registration: 02/01/2008 | SEC Registration Number: 1422142 | Stock Exchange Symbol: AADI

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

**Section 6: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

**Section 7: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

Date

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | x |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | x | |
| 1. Copy of FDA registration<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** | | ✓ | | |
| • **List of all partners and their percent ownership.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Aadi Bioscience, Inc.
Facility Name

Scott Giacobello
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

6/9/2023
Date

| Board Use Only | Date Received: 7/17/23 | Amount: 1000-CK-19161 |
|---|---|---|

**Via FedEx**

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, NV 89521

To Whom It May Concern:

On behalf of Aadi Bioscience, Inc. ("Aadi"), attached is Aadi's initial application for a license in your state.

Aadi Bioscience, Inc. is a clinical-stage biopharmaceutical company developing precision therapies for genetically-defined cancers. Aadi's primary goal is to bring transformational therapies to cancer patients with mTOR pathway driver alterations such as alterations in TSC1 or TSC2 genes, where other mTOR inhibitors have not or cannot be effectively exploited due to problems of pharmacology, effective drug delivery, safety, or effective targeting to the disease site. Aadi's lead product is FYARROTM (sirolimus albumin-bound nanoparticles for injectable suspension; nab-sirolimus; ABI-009), an mTOR inhibitor bound to human albumin that has demonstrated significantly higher tumor accumulation, greater mTOR target suppression, and increased tumor growth inhibition over other mTOR inhibitors in preclinical models. FYARRO is an investigational drug that has not been approved by the FDA for commercial distribution in the United States.

Aadi is a "Virtual Manufacturer". Their product is manufactured by a contract manufacturer and distributed by a Third-Party Logistics Provider, who meets licensure requirements to ship pharmaceutical products into your state. Therefore, at no time does Aadi physically manufacture or distribute product. Aadi's product is not a controlled substance. Accordingly, Aadi is not required to obtain a DEA registration.

In California, the definition of "Manufacture" under the California Sherman Food Drug and Cosmetic Law, Chapter 1 - General Provisions and Definitions, section 109970 defines "Manufacture" as the preparation, compounding, propagation, processing, or fabrication of any food, drug, device, or cosmetic. By this definition, Aadi is neither eligible nor required to obtain a Manufacturer's license from the state of California as it does not do any of the "preparation, compounding, propagation, processing, or fabrication" at its headquarters in Pacific Palisades, CA.

I hope this narrative is helpful as you review Aadi's application. If you have a question regarding this application, please contact me at 614-578-3827 or via email at Jordan.spadafora@twolabs.com. Please also address all written communication to me. My address is 1340 Acton Rd., Columbus, OH 43224.

Thank you in advance for your consideration.

Jordan Spadafora
*Senior Licensing Analyst*

## Description of Operations

Aadi Bioscience, Inc. is a clinical-stage biopharmaceutical company developing precision therapies for genetically-defined cancers. Aadi's primary goal is to bring transformational therapies to cancer patients with mTOR pathway driver alterations such as alterations in *TSC1* or *TSC2* genes, where other mTOR inhibitors have not or cannot be effectively exploited due to problems of pharmacology, effective drug delivery, safety, or effective targeting to the disease site. Aadi's lead product is FYARRO™ (sirolimus albumin-bound nanoparticles for injectable suspension; *nab*-sirolimus; ABI-009), an mTOR inhibitor bound to human albumin that has demonstrated significantly higher tumor accumulation, greater mTOR target suppression, and increased tumor growth inhibition over other mTOR inhibitors in preclinical models. FYARRO is an investigational drug that has not been approved by the FDA for commercial distribution in the United States.

Aadi Bioscience, Inc. ("Aadi") is a Virtual-Manufacturer located at 17383 Sunset Boulevard, Suite A250, Pacific Palisades, CA 90272. Aadi's hours of operation are 8:00am-5:00pm, M-F, Pacific Standard Time.

Aadi Bioscience, Inc. is a publicly traded company on the NSDAQ under symbol "AADI".
Tax ID# 61-1547850

## Contract Manufacturer

Aadi uses the following contract manufacturer, Fresenius Kabi USA, LLC to produce product. At no time does any contract manufacturer own Aadi's product, contract with Aadi's customers, invoice or sell Aadi's product.

Fresenius Kabi USA, LLC
3159 Staley Rd
Grand Island, NY 14072
FDA Establishment Number: 30001833549

## Third Party Logistics

Aadi's products are distributed to customers by their third-party logistics provider ("3PL"), RxCrossroads - McKesson Specialty Care Distribution, LLC. Aadi utilizes the following location for storage and distribution of their product:

RxCrossroads - McKesson Specialty Care Distribution, LLC
1001 Cheri Way, Suite 100
Fairdale, KY 40118

# Delaware

The First State



I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "AADI BIOSCIENCE, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE ELEVENTH DAY OF JANUARY, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

4459056 8300

SR# 20230107453

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202476571

Date: 01-11-23

## Company/Ownership Information

Aadi Bioscience, Inc.
17383 Sunset Boulevard, Suite A250
Pacific Palisades, CA 90272
P: 424-744-8055
E-mail: statelicensing@aadibio.com

Tax ID: 61-1547850

State of Formation: Delaware
Date Incorporated: 08/26/2021
Website: https://www.aadibio.com

Aadi Bioscience, Inc.is publicly traded on the NASDAQ
(NASDAQ Symbol: AADI)

## Officers

**Scott Giacobello, Chief Financial Officer**

**Loretta Itri, Chief Medical Officer**

**Steve Rodin, General Counsel**

**Contact information for all officers:**
17383 Sunset Boulevard, Suite A250
Pacific Palisades, CA 90272
P: 424-744-8055
E-mail: statelicensing@aadibio.com

**From:** Seid, Daniel (CDPH-FDB)
**To:** Stephanie March
**Cc:** Loui, Harlan (CDPH-FDB); Mazzera, David (CDPH-FDB)
**Subject:** RE: Sherman Definition of Manufacture
**Date:** Monday, June 26, 2017 8:05:27 PM
**Attachments:** image001.png
image002.png
image003.png

---

Dear Ms. March:

Thank you for your inquiry seeking clarification on the Department's interpretation of the Sherman Law, as it pertains to entities you have described to be "Virtual" drug manufacturers.

Your stated assumption is correct.

Best Regards,

***Daniel Seid***, **Chief**
**Drug & Consumer Product Safety Unit**

CA Dept. of Public Health
Food & Drug Branch
1500 Capitol Avenue, MS-7602
Sacramento, CA 95814
Phone: (916) 650-6619
E-Fax: (916) 440-5370
**Toll-Free: 1-800-495-3232**
www.fdb.ca.gov

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**From:** Stephanie March [mailto:Stephanie.March@pharmalicensellc.com]
**Sent:** Monday, June 19, 2017 10:18 AM
**To:** Seid, Daniel (CDPH-FDB)
**Subject:** Sherman Definition of Manufacture

Hello Daniel,

I was wondering if you could please provide some clarification as to the Department's interpretation of the definition of "Manufacture" as listed under the Sherman Food Drug and Cosmetic Law? Under Chapter 1 General Provisions and Definitions 109970 lists "Manufacture" as the preparation, compounding, propagation, processing, or fabrication of any food, drug, device, or cosmetic. The term "manufacture" does not include repackaging from a bulk container by a retailer at the time of sale to its ultimate consumer. By this definition a "Virtual Manufacturer" (meaning a company who owns the drug's NDA but utilizes a CMO to manufacture, therefore no drugs are ever on the Virtual Manufacturer's property) would not be eligible to obtain a Manufacturer's license from the state of California as it does not do any of the "preparation, compounding, propagation, processing, or fabrication." Is that a correct assumption of the Department's interpretation of this definition?

Confidential Information - Do Not Distribute

**Employee List**

Jackie Bushong
Tom DeMelfi
Ayeshna Desai
Neil Desai
John Glennon
Carmen Gordon
Marcy Graham
Samuel Higbie
Andrew Kwon
Angelyn Maltzman
Brian McMorran

The content of this message is confidential and it not to be used beyond its intended use.

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**
**Pursuant to Section 13 or 15(d)**
**of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): June 14, 2023**

# AADI BIOSCIENCE, INC.
**(Exact name of registrant as specified in its charter)**

| Delaware | 001-38560 | 61-1547850 |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (I.R.S. Employer Identification No.) |

| 17383 Sunset Boulevard, Suite A250<br>Pacific Palisades, California | 90272 |
|---|---|
| (Address of principal executive offices) | (Zip code) |

**Registrant's telephone number, including area code: (424) 744-8055**
**(Former name or former address, if changed since last report.)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| **Common Stock, par value $0.0001 per share** | **AADI** | **The Nasdaq Stock Market LLC** |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

**Item 5.07. Submission of Matters to a Vote of Security Holders.**

Aadi Bioscience, Inc. (the "Company") held its annual meeting of stockholders on June 14, 2023 (the "Annual Meeting"). At the Annual Meeting, 13,926,204 shares of common stock of the Company, representing approximately 57% of the voting power of all issued and outstanding shares of common stock of the Company as of April 25, 2023, the record date for the Annual Meeting, and constituting a quorum for the transaction of business, were present in person or by proxy and considered and voted on the following proposals, each of which is described in more detail in the Company's definitive proxy statement for the Annual Meeting filed with the Securities and Exchange Commission on April 28, 2023 (the "Proxy Statement"): (1) the election of three Class III directors for terms to expire at the Company's 2026 annual meeting of stockholders and until their respective successors have been duly elected and qualified; (2) on an advisory basis, the compensation of the named executive officers identified in the 2022 Summary Compensation Table in the "Executive Compensation" section of the Proxy Statement (the "Say-on-Pay Vote"); (3) on an advisory (non-binding) basis, the frequency of future Say-on-Pay Votes; and (4) the ratification of the appointment of BDO USA LLP as the Company's independent registered public accounting firm for the current fiscal year ending December 31, 2023.

The voting results at the Annual Meeting with respect to each of the matters described above were as follows:

**Proposal 1:** Election of three Class III directors to serve until the 2026 Annual Meeting of Stockholders and until their respective successors have been elected or qualified.

| Director | For | Withheld | Broker Non-Votes |
|---|---|---|---|
| Behzad Aghazadeh, Ph.D. | 8,361,137 | 1,669,427 | 3,895,640 |
| Richard Maroun | 9,872,401 | 158,163 | 3,895,640 |
| Emma Reeve | 9,871,998 | 158,566 | 3,895,640 |

**Proposal 2:** To approve, on an advisory basis, the compensation of the named executive officers identified in the 2022 Summary Compensation Table in the "Executive Compensation" section of the Proxy Statement.

| For | Against | Abstentions | Broker Non-Votes |
|---|---|---|---|
| 9,738,074 | 275,337 | 17,153 | 3,895,640 |

**Proposal 3:** To approve, on an advisory (non-binding) basis, the frequency of future Say-on-Pay Votes.

| 1 Year | 2 Years | 3 Years | Abstentions | Broker Non-Votes |
|---|---|---|---|---|
| 9,832,520 | 2,546 | 75,231 | 120,267 | N/A |

In accordance with the voting results for this proposal, the Company has determined that the Company will hold future stockholder advisory votes on the compensation of the Company's named executive officers every year. The next required advisory vote on the frequency of future stockholder advisory votes on the compensation of the Company's named executive officers will take place no later than at the Company's 2029 annual meeting of stockholders.

**Proposal 4:** Ratification of the appointment of BDO USA LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2023.

| For | Against | Abstentions |
|---|---|---|
| 13,850,448 | 72,970 | 2,786 |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

June 14, 2023

*/s/ Scott Giacobello*

Scott Giacobello

Interim Chief Executive Officer and President, and Chief Financial Officer

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

# National Drug Code Directory

Current through June 28, 2023

**You have searched Finished drug products**

**Search Results**: *'80803'*

Back to Search Page () | Search Again ()

CSV Excel

**Display** 50 **records per page** **Search for text in the table:**

| Proprietary Name | NDC Package Code | Strength | Dosage Form | Route | Appl. No. | Labeler Name | Product NDC | Nonproprietary Name | Substance Name | Product Type Name | Start Marketing Date | End Market Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + FYARRO | 80803-153-50 | 5 mg/mL | INJECTION, POWDER, LYOPHILIZED, FOR SUSPENSION | INTRAVENOUS | NDA213312 | Aadi Bioscience | 80803-153 | Sirolimus | SIROLIMUS | HUMAN PRESCRIPTION DRUG | 11/22/2021 | N/A |

Showing 1 to 1 of 1 entries Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)

See also: Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

√ Verified 7/27/23

# 4DD

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application
## Non-Refundable $1,000 Fee

Rev (08/17/2022)

| | |
|---|---|
| **Where is the facility located?** | ☐ Nevada ☑ Out-of-State |
| **Type of Application (check applicable box)** | **Wholesaler Business Type (check applicable box)** |
| ☑ New Wholesaler<br>☐ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only)<br><br>* If making a change, provide current license number: N/A<br>WH _____ | ☑ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: Boston Scientific Corporation

Physical Address: 10700 Xylon Ave North

City: Brooklyn Park State: MN Zip: 55455

Mailing Address (if different from physical address): 4100 Hamline Ave N.

City: Saint Paul State: MN Zip: 55112

Telephone: 651-582-4000 Website: http://www.bostonscientific.com

Name of Designated Representative (DR): Daniel Kohout

Licensing Company Email: STPDrugLicensing@bsci.com DR Email: Daniel.kohout@bsci.com

| Entities the Wholesaler will Serve (✓ all applicable) | Products to be Handled or Wholesaled (✓ all applicable) | Type of Wholesaling (✓ all applicable) |
|---|---|---|
| ☐ Pharmacies | ☐ Dangerous Drugs | ☐ Manufacturer |
| ☑ Practitioners | ☐ Controlled Substances | ☐ Repacker |
| ☐ Hospitals | ☑ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ☐ Wholesalers | ☐ Others: | ☐ Warehouse |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ☑ Others: Clinics | | ☑ Others: Wholesale Distributor |

| Section 2: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | X |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | X |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | X |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | X |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | X |

N/A

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

N/A
Original Signature (electronic, copies or stamps not accepted)

N/A
Date

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: N/A - No pharmaceuticals products are handled or sold. See Attachment A.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

**Section 4: Publicly Traded Corporation**

State of Incorporation: Delaware

Parent Company (if any): N/A - Publicly Traded

Corporation Name: Boston Scientific Corporation

Mailing Address: 300 Boston Scientific Way

City: Marlborough State: MA Zip: 01752

Telephone: (800) 876-9960 Email: Erik.Walder@bsci.com

Contact Person Name: Erik Walder

Date of SEC Registration: 6/22/1979 | SEC Registration Number: CIK#: 0000885725 | Stock Exchange Symbol: BSX

**Section 5: Non-Publicly Traded Corporation or Company** N/A

State of Incorporation/Organization: N/A

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

**Section 6: Partnership**

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

**Section 7: Sole Owner**

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | X |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | | X |
| 1. Copy of FDA registration<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** See Attachment C | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** See Attachment C | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** N/A | | ✓ | | |
| • **List of all partners and their percent ownership.** N/A | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment B | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - not required for publicly traded companies. | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** N/A | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) See Attachment D | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment E | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** N/A - See Attachment F | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ See Attachment G | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). See Attachment H | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. N/A - publicly traded company. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. N/A - publicly traded company. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Boston Scientific Corporation

Facility Name

Daniel Kohout

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

26-JUN-2023

Date

| Board Use Only | Date Received: 6/28/23 | Amount: 1000 - CK - 889 |
|---|---|---|

## Attachment A

## Nature of Business

Boston Scientific Corporation (BSC) is a publicly traded company and worldwide developer, manufacturer, and marketer of medical devices. BSC's North Park, MN facility is a wholesale distributor of non-prescription and prescription medical devices. Its hours of operations are 6:00 am – 10:00 pm CST, Monday through Friday. This facility intends to distribute medical devices to physicians, hospitals, and clinics. Listed below are the facilities that manufacture product distributed by North Park.

Lumenis Be Ltd
Yokneam Industrial Park, Hakidma Street 6,
Yokneam 2069204, Israel
FDA Registration #: 3021349626

STELLARTECH RESEARCH CORPORATION
560 COTTONWOOD DRIVE, MILPITAS, CA 95035
FDA Registration #: 3010653929

Boston Scientific Corporation
4100 Hamline Ave N, Arden Hills, MN, 55112
FDA Registration #: 2124215

NORTHGATE TECHNOLOGIES INC
1591 SCOTTSDALE COURT, ELGIN, IL 60123
FDA Registration #: 1450997

DT Research Inc
6F., No. 36, Wuquan 7th Rd., Wugu Dist., New Taipei City 24890, Taiwan
FDA Registration #: 3017233611

Modo, Inc.
9025 NW Von Neumann Drive, #170, Hillsboro, OR 97006
FDA Registration #: 3004636440

ENERCON TECHNOLOGIES
25 NORTHBROOK DR. GRAY, ME 04039
FDA Registration #: 3003018722

Trice Medical Inc.
40 General Warren Boulevard, Suite 100,
Malvern, PA 19355
FDA registration #: 3010760216

LINEMASTER SWITCH CORPORATION
29 Plaine Hill Road. Woodstock, CT 06281
FDA Registration #: 3001592626

Microtek Medical Inc
Las Americas Free Zone, KM 22 Las Americas Highway
Santo Domingo, Dominican Republic 22000
FDA Registration #: 3012811961

Creation Technologies Ltd
8977 – 8999 Fraserton Court, Burnaby, British Columbia, V5J 5H8, Canada
FDA Registration #: 3000279201

Electro Medical Systems
11886 Greenville Avenue, #120, Dallas, TX 75243
FDA Registration #: 1648564

Electro Medical Systems
De La Vuarpilliere 31, Nyon, Switzerland 1260
FDA Registration #: 1648564

AMPHENOL DC ELECTRONICS
1870 Little Orchard Street, San Jose, CA 95125
FDA Registration #: 3001763079

Jabil Shanghai
600 Tianlin Road, Shanghai 200233
FDA Registration #: 3005210579

FDA

FDA Home[3] Medical Devices[4] Databases[5]

## Establishment Registration & Device Listing

New Search

Back To Search Results

**Establishment:**
Boston Scientific Corporation
10700 Xylon Av N
Minneapolis, MN 55455
**Registration Number:** 3027345794
**FEI Number*:** 3027345794
**Status:** Active
**Initial Distributor/Importer:** Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
**Date Of Registration Status:** 2023

**Owner/Operator:**
Boston Scientific Corporation[6]
300 Boston Scientific Way
Marlborough, MA US 01752
**Owner/Operator Number:** 9912058[7]

**Official Correspondent:**
Adrienne Bishop
300 Boston Scientific Way
Marlborough, MA 01752
**Phone:** 763-4941588

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9912058&OwnerOperator
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=9912058&OwnerOperator

Page Last Updated: 06/26/2023

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Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

# FORM 10-K

☑ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934, or

For the fiscal year ended December 31, 2022

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File No. 1-11083

# BOSTON SCIENTIFIC CORPORATION

(Exact name of registrant as specified in its charter)

| Delaware | 04-2695240 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |

| 300 Boston Scientific Way, Marlborough, Massachusetts | 01752-1234 |
|---|---|
| (Address of Principal Executive Offices) | (Zip Code) |

508 683-4000
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock, $0.01 par value | BSX | New York Stock Exchange |
| 0.625% Senior Notes due 2027 | BSX27 | New York Stock Exchange |
| 5.50% Mandatory Convertible Preferred Stock, Series A, par value $0.01 per share | BSX PR A | New York Stock Exchange |

Securities registered pursuant to Section 12(g) of the Act:
NONE

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes: ☑ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes: ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes: ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorted period that the registrant was required to submit such files). Yes: ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

| | | | |
|---|---|---|---|
| Large accelerated filer | ☑ | Accelerated filer | ☐ |
| Non-accelerated filer | ☐ | Smaller reporting company | ☐ |
| | | Emerging growth company | ☐ |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☑
If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes: ☐ No ☑

The aggregate market value of the registrant's common stock held by non-affiliates was approximately $53.2 billion based on the last reported sale price of $37.27 of the registrant's common stock on the New York Stock Exchange on June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter. (For this computation, the registrant has excluded the market value of all shares of common stock of the registrant reported as beneficially owned by executive officers, and directors of the registrant; such exclusion shall not be deemed to constitute an admission that any such person is an affiliate of the registrant.)

The number of shares outstanding of Common Stock, $0.01 par value per share, as of January 31, 2023 was 1,434,780,104.

Documents Incorporated by Reference

Portions of the registrant's definitive proxy statement to be filed within 120 days of December 31, 2022 with the Securities and Exchange Commission in connection with its 2023 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K.

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# PART I

## ITEM 1. BUSINESS

### Our Company

Boston Scientific Corporation is a global developer, manufacturer and marketer of medical devices that are used in a broad range of interventional medical specialties. Our mission is to transform lives through innovative medical solutions that improve the health of patients around the world. As a medical technology leader for more than 40 years, we have advanced the practice of less-invasive medicine by helping physicians and other medical professionals diagnose and treat a wide range of diseases and medical conditions and improve patients' quality of life by providing alternatives to surgery and other medical procedures that are typically traumatic to the body. We advance science for life by providing a broad range of high performance solutions to address unmet patient needs and reduce the cost of healthcare. When used in this report, the terms "we," "us," "our" and "the Company" mean Boston Scientific Corporation and its divisions and subsidiaries.

### Business Strategy

We operate pursuant to five strategic imperatives. We aim to: Strengthen Category Leadership, Expand into High Growth Adjacencies, Drive Global Expansion, Fund the Journey to Fuel Growth and Develop Key Capabilities. We believe that our execution of these strategic imperatives will help us deliver on our mission, drive innovation and increase value for our customers and employees, while strengthening our leadership position in the medical device industry and delivering profitable revenue growth.

We expect to continue to invest in our core franchises and pursue opportunities to diversify and further expand our presence in strategic, high-growth adjacencies and new global markets, including growth within the countries we define as emerging markets. Maintaining and expanding our international presence is an important component of our long-term growth strategy. Through our international presence, we seek to increase net sales and market share, leverage our relationships with leading physicians and their clinical research programs, accelerate the time to bring new products to market and gain access to worldwide technological developments that we can implement across our product lines. Our research and development efforts are focused largely on the development of next-generation and novel technology offerings across multiple programs and all divisions. In the past several years, we have completed numerous acquisitions in support of our growth strategy, both strengthening our core franchises and expanding into high growth adjacent markets. We continue to develop digital tools and technologies that enable us to compete more effectively and deliver first class remote physician education, drive deeper patient engagement and increase digitally-enabled sales force productivity.

We have a firm commitment to corporate social responsibility and living our values as a global business and global corporate citizen. This includes taking actions to combat discrimination and advancing equality and diversity, including through financial support of racial equity initiatives in the communities where we live and work, protecting the environment, investing in our employees' health and well-being, and many other initiatives that we believe ultimately help us create value responsibly. Refer to discussion of *Community Outreach* below and *Corporate Sustainability* included in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations of this Annual Report on Form 10-K for additional information regarding measures we are undertaking.

### Product Offerings

Our core businesses are organized into two reportable segments: MedSurg and Cardiovascular. The following describes our key product offerings and new product innovations by reportable segment.

#### MedSurg

*Endoscopy*

Our Endoscopy business develops and manufactures devices to diagnose and treat a broad range of gastrointestinal and pulmonary conditions with innovative, less invasive technologies. Our product offerings include the following:

- Resolution 360™ Clips and Resolution 360™ ULTRA Clips, hemostatic clipping technology designed to stop and help prevent bleeding during endoscopic procedures,
- WallFlex™ Biliary Stent Systems, used for relieving biliary obstructions by providing bile drainage in both malignant and benign strictures,

- AXIOS™ Stents and Electrocautery Enhanced Delivery Systems, the first, and currently only stents systems in the U.S. indicated for endoscopic drainage of pancreatic pseudocysts,
- SpyGlass™ DS II Direct Visualization Systems and SpyGlass™ Discover Digital Catheters, the first single-use scopes to enable physicians to take a single-stage approach to diagnostic and therapeutic procedures in the pancreaticobiliary system, including treating patients with bile duct stones,
- EXALT™ Model D Single-Use Duodenoscopes for use in endoscopic retrograde cholangiopancreatography (ERCP) procedures, the first U.S. Food and Drug Administration (FDA)-cleared single-use (disposable) duodenoscopes on the market,
- Acquire™ Endoscopic Ultrasound Fine Needle Biopsy Devices, which are designed to obtain larger tissue specimens for histological assessment and diagnosis of diseases such as pancreatic cancer, liver cancer and stomach lesions and
- our infection prevention portfolio, designed to minimize the risk of infection transmission and improve operational efficiencies by streamlining manual cleaning or eliminating the need for cleaning and tracking.

*Urology*

Our Urology business develops and manufactures devices to treat various urological and pelvic conditions for both male and female anatomies, including kidney stones, benign prostatic hyperplasia (BPH), prostate cancer, erectile dysfunction and incontinence. Our product offerings include the following:

- a comprehensive line of stone management products, including ureteral stents, catheters, baskets, guidewires, sheaths and balloons,
- LithoVue™ Single-Use Digital Flexible Ureteroscopes, which deliver detailed high-resolution digital images for high-quality visualization and seamless navigation,
- Lumenis Pulse™ Holmium Laser Systems with MOSES™ Technology, complemented by a full line of laser fibers and accessories used in urology and otolaryngology procedures,
- our Prosthetic Urology portfolio, which includes AMS 700™, our penile implants to treat erectile dysfunction and AMS 800™, our urinary control systems to treat male urinary incontinence,
- GreenLight XPS™ Laser System, MoXy™ Fiber, and Rezūm™ Systems for treatment of BPH and
- SpaceOAR™ Hydrogel Systems which help reduce side effects that men may experience after receiving radiotherapy to treat prostate cancer, together with our SpaceOAR VUE™ Hydrogel, providing clinicians with enhanced product visualization.

In the third quarter of 2022, we launched the Rezūm™ Water Vapor Therapy System in Japan following regulatory approval from Japan's Ministry of Health, Labor and Welfare (MHLW) and received approval of a new reimbursement category from Japan's Central Social Insurance Medical Counsel (Chuikyo) for both the device and procedure.

In the first quarter of 2023, we received FDA clearance for and will begin a limited market release of our LithoVue™ Elite Single-Use Digital Flexible Ureteroscope System, the first ureteroscope system with the ability to monitor intrarenal pressure in real-time during ureteroscopy procedures.

*Neuromodulation*

Our Neuromodulation business develops and manufactures devices to treat various neurological movement disorders and manage chronic pain. Our product offerings include the following:

- Precision Montage™ and WaveWriter Alpha™ Spinal Cord Stimulator (SCS) Systems, designed to provide improved pain relief to a wide range of patients who suffer from chronic pain, with proprietary features such as Multiple Independent Current Control, our Illumina 3D™ Proprietary Programming Software and FAST™ Therapy for profound parathesia-free pain relief in minutes, used by physicians to target specific areas of pain and customize stimulation of nerve fibers more precisely,
- our G4™ Generator and consumable portfolio in Radiofrequency Ablation (RFA) for pain management used by physicians to treat patients with chronic pain,
- Our Cognita™ Practice Optimization suite of tools designed to increase awareness, streamline patient management, and sustain long-term outcomes for patients,
- Vercise Gevia™ and Vercise Genus™ Deep Brain Stimulation (DBS) Systems for the treatment of Parkinson's disease, tremor, and intractable primary and secondary dystonia, a neurological movement disorder characterized by involuntary muscle contractions and

- Superion™ Indirect Decompression Systems, minimally-invasive devices used to improve physical function and reduce pain in patients with moderate lumbar spinal stenosis (LSS).

Our Vercise™ DBS Systems are approved in the U.S. as an adjunctive therapy that aids in reducing some of the symptoms of moderate to advanced Parkinson's disease as well as for patients diagnosed with essential tremor. The Vercise Genus™ DBS platform features a full portfolio of primary cell and rechargeable MRI conditional systems with Bluetooth connectivity and the Cartesia™ Directional Lead, providing multi-directional stimulation designed for greater precision, intended to minimize side effects for patients. In 2022, we further expanded our portfolio with Image Guided Programming with the US release of Stimview™ XT, a proprietary DBS visualization software developed in collaboration with Brainlab AG, providing clinicians with real-time, 3D visualization and stimulation of brain anatomy.

Cardiovascular

*Cardiology*

*Interventional Cardiology Therapies (ICTx)*

Our Interventional Cardiology Therapies business develops and manufactures technologies for diagnosing and treating coronary artery disease and aortic valve conditions. Our product offerings include the following:

- OptiCross™ IVUS Imaging Catheters,
- iLab™ Ultrasound Imaging Systems with Polaris Software, designed to enhance the diagnosis and treatment of blocked vessels and other heart disorders, compatible with our full line of imaging catheters,
- AVVIGO™ Guidance Systems and AVVIGO™ Guidance System II, incorporating high-definition IVUS all in a mobile or integrated platform,
- ROTAPRO™ Rotational Atherectomy Systems, which regulate the flow of air to the advancer, controlling burr rotation speed, and also monitor and display burr rotation speed and rotational atherectomy procedural time,
- SYNERGY™, SYNERGY MEGATRON™ and SYNERGY™ XD Everolimus-Eluting Platinum Chromium Coronary Stent Systems, featuring an ultra-thin abluminal (outer) bioabsorbable polymer coating,
- Safari2™ Pre-Shaped Guidewires, intended to facilitate the introduction and placement of interventional devices within the heart,
- ACURATE *neo2*™ Aortic Valve Systems for use in transcatheter aortic valve replacement (TAVR) procedures and
- SENTINEL™ Cerebral Embolic Protection Systems, used to reduce the risk of stroke in TAVR procedures and is clinically proven to decrease cerebral embolization and its associated neurological effects.

*Watchman*

Our WATCHMAN FLX™ Left Atrial Appendage Closure (LAAC) Devices are designed to close the left atrial appendage in patients with non-valvular atrial fibrillation who are at risk for ischemic stroke. WATCHMAN™ is the first device to offer a non-pharmacologic alternative to oral anti-coagulants that has been studied in a randomized clinical trial and is the leading device in percutaneous LAAC globally.

*Cardiac Rhythm Management*

Our Cardiac Rhythm Management (CRM) business develops and manufactures a variety of implantable devices that monitor the heart and deliver electricity to treat cardiac abnormalities. Our product offerings include the following:

- the RESONATE™ family of implantable cardioverter defibrillators (ICD) and implantable cardiac resynchronization therapy defibrillators (CRT-D), including our proprietary HeartLogic™ Heart Failure (HF) Diagnostic and SmartCRT™ Technology with Multisite pacing in CRT-D,
- EMBLEM™ MRI S-ICD System, the world's first, and currently only, commercially available subcutaneous implantable cardiac defibrillators (S-ICD), which provides physicians the ability to treat patients who are at risk for sudden cardiac arrest without touching the heart,
- ACCOLADE™ family of pacemakers and implantable cardiac resynchronization therapy pacemakers (CRT-P),
- ACUITY™ X4 Quadripolar LV Leads, RELIANCE™ family of ICD Leads and our INGEVITY™ Pacing Leads,
- LATITUDE™ Remote Patient Management Systems, which allow for more frequent monitoring and better guided treatment decisions by enabling physicians to monitor implantable system performance remotely,

- LUX-Dx™ Insertable Cardiac Monitor (ICM) systems, long-term diagnostic devices implanted in patients to detect arrhythmias associated with conditions such as atrial fibrillation (AF), cryptogenic stroke and syncope and
- BodyGuardian™ remote cardiac monitoring systems provide a full range of mobile health solutions and remote monitoring services, ranging from ambulatory cardiac monitors – including short and long-term holter monitors – to cardiac event monitors and mobile cardiac telemetry.

Our entire transvenous defibrillator portfolio leverages our EnduraLife™ Battery Technology and has magnetic resonance imaging (MRI) conditional labeling when used with our current generation of leads.

*Electrophysiology*

Our Electrophysiology business develops and manufactures less-invasive medical technologies used in the diagnosis and treatment of rate and rhythm disorders of the heart, including a broad portfolio of therapeutic and diagnostic catheters and a variety of equipment used in the Electrophysiology lab. Our product offerings include the following:

- Rhythmia™ Mapping Systems, catheter-based, 3-D cardiac mapping and navigation solutions designed to help diagnose and guide treatment of a variety of arrhythmias,
- cardiac ablation catheters including the Blazer™, IntellaNav™, IntellaNav Stablepoint™ and IntellaTip MiFi Open-Irrigated Ablation Catheter families, featuring a unique Total Tip Cooling™ Design and DIRECTSENSE™ Software for monitoring radiofrequency (RF) energy delivery during procedures,
- IntellaMap Orion™ Mapping Catheters, for use with our Rhythmia Mapping System to provide high-density, high-resolution maps of the heart,
- Farapulse™ Pulsed Field Ablation (PFA) Systems for the treatment of atrial fibrillation (AF),
- POLARx™ Cryoablation Systems for the treatment of AF and
- intracardiac ultrasound catheters, delivery sheaths and other accessories

On February 14, 2022, we completed our acquisition of Baylis Medical Company, Inc (Baylis Medical), which has developed the radiofrequency (RF) NRG™ and VersaCross™ Transseptal Platforms as well as a family of guidewires, sheaths and dilators used to support left heart access, which expands our electrophysiology and structural heart product portfolios. In the second quarter of 2022, we received FDA 510(k) clearance for and launched the VersaCross Connect™ LAAC Access Solution developed by Baylis Medical, providing safe and efficient access to the left side of the heart.

*Peripheral Interventions*

Our Peripheral Interventions business develops and manufactures products to diagnose and treat peripheral arterial and venous diseases, as well as products to diagnose, treat and ease various forms of cancer. Our broad peripheral portfolio includes stent systems, balloon catheters, guidewires, atherectomy and thrombectomy systems, embolization devices, radioactive microspheres, radiofrequency and cryotherapy ablation systems, microcatheters and drainage catheters.

Our peripheral arterial product offerings include:

- EPIC™ and Innova™ Self-Expanding Stent Systems,
- Eluvia™ Drug Eluting Vascular Stent Systems, innovative stents built on the Innova stent platform, designed to deliver a sustained dosage of paclitaxel during the time when restenosis is most likely to occur,
- Mustang™, Coyote™ and Sterling™ PTA Balloon Catheters designed for a wide variety of peripheral angioplasty procedures and
- Ranger™ Drug-Coated Balloons, innovative balloons built on the Sterling balloon platform, featuring a low-dose of paclitaxel.

In the third quarter of 2022, we launched an ELUVIA™ line extension, introducing the longest-length available for treatment of patients with peripheral artery disease (PAD) in the superficial femoral artery. We are also the first company to provide physicians with both a drug-eluting stent and drug-coated balloon option for the treatment of patients with PAD.

Our venous disease product offerings include the following:

- •AngioJet™ Thrombectomy Systems, used in endovascular procedures to remove blood clots from blocked arteries and veins and our AngioJet Zelante DVT™ Thrombectomy Catheters to treat deep vein thrombosis,
- •WOLF Thrombectomy™ Platform, which is designed to mechanically remove the clots without damaging blood vessels, while also minimizing blood loss,
- •EKOS™ Ultrasound Assisted Thrombolysis systems used to treat pulmonary embolisms and
- •Varithena™ Polidocanol Injectable Foam used to improve the symptoms of superficial venous incompetence and the appearance of visible varicosities.

Our interventional oncology product offerings include the following:

- •TheraSphere™ Y-90 radioactive glass microspheres used in the treatment of hepatocellular carcinoma (HCC), the most common type of liver cancer,
- •Renegade™ HI-FLO™ Fathom™ Microcatheter and Guidewire System and Interlock™ - 35 Fibered IDC™ and 18 Fibered IDC™ Occlusion System for peripheral embolization,
- •EMBOLD™ Detachable Coil System, used for arterial and venous embolizations in the peripheral vasculature, and
- •ICEFX™ and Visual ICE™ Cryoablation Systems for destruction of tissue, using image-guided needles to enable cryoablation visualization for optimal tumor coverage.

Markets

*Competition*

We encounter significant competition across our product lines and in each market in which we sell our products and solutions, some from companies that may have greater financial, sales and marketing resources than we do. Our primary competitors include Abbott Laboratories and Medtronic plc, as well as a wide range of medical device companies that sell a single or limited number of competitive products or participate in only a specific market segment. In certain countries, and particularly in China, we also face competition from domestic medical device companies that may benefit from their status as local suppliers. We also face competition from non-medical device companies, which may offer alternative therapies for disease states that could also be treated using our products, or from companies offering technologies that could augment or replace procedures using our products.

We believe that our products and solutions compete primarily on their ability to deliver both differentiated clinical and economic outcomes for our customers by enabling physicians to perform diagnostic and therapeutic procedures safely and effectively often in a less-invasive and cost effective manner. We also compete on ease of use, comparative effectiveness, reliability and physician familiarity. In the current environment of managed care, with economically motivated buyers, consolidation among healthcare providers, increasing prevalence and importance of regional and national tenders, increased competition and declining reimbursement rates, we have been increasingly required to compete on the basis of price, value, reliability and efficiency. We believe the current global economic conditions and healthcare reform measures could continue to put additional competitive pressure on us, including on our average selling prices, overall procedure rates and addressable market sizes. We recognize that our continued competitive success will depend upon our ability to:

- •offer products and solutions that provide differentiated clinical and economic outcomes,
- •create or acquire innovative, scientifically advanced technologies,
- •apply our technology and solutions cost-effectively and with superior quality across product lines and markets,
- •develop or acquire proprietary products and solutions,
- •attract and retain qualified personnel,
- •obtain patent or other protection for our products,
- •obtain required regulatory and reimbursement approvals,
- •continually provide quality products and enhance our quality systems,
- •supply sufficient inventory at competitive prices to meet customer demand.

*Research and Development*

Our investment in research and development is critical to driving our future growth. Our investment in research and development supports the following:

- internal research and development programs, regulatory design and clinical science, as well as other programs obtained through our strategic acquisitions and alliances, and
- engineering efforts that incorporate customer feedback into continuous improvement efforts for currently marketed and next-generation products.

We have directed our development efforts toward innovative technologies designed to expand current markets or enter adjacent markets. We continue to transform how we conduct research and development by identifying best practices, driving efficiencies and optimizing our cost structure, which we believe will enable increased development activity and faster concept-to-market timelines. Focused, cross-functional teams take a formal approach to new product design and development, helping us to manufacture and offer innovative products consistently and efficiently. Involving cross-functional teams early in the process is the cornerstone of our product development cycle. We believe this collaboration allows our teams to concentrate resources on the most viable and clinically relevant new products and technologies and to maximize cost and time savings as we bring them to market.

In addition to internal development, we work with hundreds of leading research institutions, universities and clinicians around the world to develop, evaluate and clinically test our products. We continue to expand our collaborations to include research and development teams in our emerging market countries; these teams will focus on both global and local market requirements at a lower cost of development. We believe that these efforts will play a significant role in our future success.

*Marketing and Sales*

In 2022, we marketed our products and solutions to approximately 36,000 hospitals, clinics, outpatient facilities and medical offices in 130 countries worldwide. Large group purchasing organizations, hospital networks and other buying groups have become increasingly important to our business and represent a substantial portion of our net sales. Each of our businesses maintains dedicated sales forces and marketing teams focused on physicians who specialize in the diagnosis and treatment of different medical conditions, as well as on key hospital service line administrators.

The majority of our net sales are derived from countries in which we have direct sales organizations. We also have a network of distributors and dealers who offer our products in certain countries and markets. We expect to continue to leverage our infrastructure in markets where commercially appropriate and use third party distributors in those markets where it is not economical or strategic to establish or maintain a direct presence.

Resources

*Manufacturing and Raw Materials*

We are focused on continuously improving our supply chain effectiveness, strengthening our manufacturing processes and increasing operational efficiencies within our organization worldwide. In doing so, we seek to focus our internal resources on the development and commercial launch of new products and the enhancement of existing products. We also drive continuous improvement in product quality through process controls and validations, supplier and distribution controls and training and tools for our operations team. In addition, we remain focused on examining our operations and general business activities to enhance our operational effectiveness by identifying cost-improvement opportunities.

We remain committed to maintaining appropriate investments to ensure supply chain stability. We have an ongoing supplier resiliency program which identifies and mitigates risk and have taken measures to mitigate the impact of challenges within the global supply chain, including those caused in part by the COVID-19 pandemic. We consistently monitor our inventory levels, manufacturing, sterilization and distribution capabilities and partnerships and maintain recovery plans to address potential disruptions. Many components used in the manufacturing of our products are readily fabricated from commonly available raw materials or off-the-shelf items available from multiple supply sources; however, certain items are custom made to meet our specifications.

On an on-going basis, we track supplier status and inventory in risk areas and take action to prevent shortages, monitoring safety stock levels and building up product supplies as warranted, and mitigating risk of technology and material shortages by identifying new vendors.

We have experienced increased levels of unpredictability in the supply of certain raw materials and components used in the manufacturing of our products. While we continue to believe we will have access to the raw materials and components that we need, these supply chain dynamics could result in increased costs to us or an inability to fully meet customer demand for certain of our products.

*Proprietary Rights and Patent Litigation*

We rely on a combination of patents, trademarks, trade secrets and other forms of intellectual property to protect our proprietary rights. We generally file patent applications in the U.S. and other countries where patent protection for our technology is appropriate and available. We hold patents worldwide that cover various aspects of our technology. In addition, we hold exclusive and non-exclusive licenses to a variety of third-party technologies covered by patents and patent applications. In the aggregate, these intellectual property assets and licenses are of material importance to our business; however, we believe that no single patent, technology, trademark, intellectual property asset or license is material in relation to our business as a whole.

We rely on non-disclosure and non-competition agreements with employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology. There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry, particularly in the areas in which we compete. We continue to defend ourselves against claims and legal actions alleging infringement of the patent rights of others. Additionally, we may find it necessary to initiate litigation to enforce our patent rights, to protect our trade secrets or know-how and to determine the scope and validity of the proprietary rights of others. Accordingly, we may seek to settle some or all of our pending litigation, particularly to manage risk over time. Settlement may include cross licensing of the patents that are the subject of the litigation as well as our other intellectual property and may involve monetary payments to or from third parties.

We maintain insurance policies providing limited coverage against securities claims. We are substantially self-insured with respect to product liability claims and fully self-insured with respect to intellectual property infringement claims. The absence of significant third-party insurance coverage increases our potential exposure to unanticipated claims or adverse decisions. See *Note I – Commitments and Contingencies* to our 2022 consolidated financial statements included in Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K for a discussion of intellectual property, product liability and other litigation and proceedings in which we are involved.

Regulatory Environment

*Medical Device Regulatory Approvals*

The medical devices that we manufacture, market and commercialize are subject to regulation by numerous worldwide regulatory bodies, including the U.S. FDA and comparable international regulatory agencies. These agencies require manufacturers of medical devices to comply with applicable laws and regulations governing development, testing, manufacturing, labeling, marketing and distribution. Medical devices are also generally subject to varying levels of regulatory control based on risk level of the device.

In the U.S., authorization to distribute a new device can generally be met in one of two ways. The first process requires that a premarket notification (510(k)) be made to the FDA to demonstrate that the device is as safe and effective as, or substantially equivalent to, a legally marketed device (the "predicate" device). Applicants must submit performance data to establish substantial equivalence. In some instances, data from human clinical trials must also be submitted in support of a 510(k) premarket notification. If so, these data must be collected in a manner that conforms to the applicable Investigational Device Exemption (IDE) regulations. The FDA must issue a decision finding substantial equivalence before commercial distribution can occur. Changes to cleared devices that could not significantly affect the safety or effectiveness of the device can generally be made without additional 510(k) premarket notifications; otherwise, a new 510(k) is required.

The second process requires the submission of a premarket approval (PMA) application to the FDA to demonstrate that the device is safe and effective for its intended use. This approval process applies to most Class III devices and generally requires clinical data to support the safety and effectiveness of the device, obtained in adherence with IDE requirements. The FDA will approve the PMA application if it finds that there is a reasonable assurance that the device is safe and effective for its intended purpose and that the proposed manufacturing is in compliance with the Quality System Regulation (QSR). For novel technologies, the FDA may seek input from an advisory panel of medical experts and seek their views on the safety, effectiveness and benefit-risk of the device. The PMA process is generally more detailed, lengthier and more expensive than the 510(k) process.

In the European Union (EU), we are required to comply with the Medical Device Regulation (MDR or EU MDR) which became effective May 2021, superseding the existing Medical Device and Active Implantable Medical Device Directives. Medical devices which have a valid CE Certificate to the prior Directives (issued before May 2021) can continue to be sold during the applicable transition period or until the CE Certificate expires, whichever comes first, providing there are no significant changes to the design or intended use. The CE Mark, which is required to sell medical devices in the EU is affixed following a Conformity Assessment and either approval from the appointed independent Notified Body or through self-certification by the manufacturer. The selected pathway to CE marking is based on device risk classification. CE marking indicates conformity to the applicable General Safety and Performance Requirements (GSPRs) for the MDR. The MDR changes multiple aspects of the regulatory framework for CE marking, such as increased clinical evidence requirements, changes to labelling, and new requirements, including Unique Device Identification (UDI), and many new post-market reporting obligations. MDR also modifies and increases the compliance requirements for the medical device industry and will continue to require significant investment over the next few years to transition all products. The CE mark continues to be a prerequisite for successful registration in many other global geographies. In addition, other EU countries continue to impose significant local registration requirements despite the implementation of MDR, and the United Kingdom has introduced new requirements following its exit from the EU.

We are also required to comply with the regulations of every other country where we commercialize products before we can launch or maintain new products on the market, including regulations that have been introduced in many countries in the Middle East and Southeast Asia that previously did not have medical device regulations, or had minimal regulations. In Japan we are required to comply with Japan's Ministry of Health, Labor and Welfare (MHLW) regulations. In conjunction with the MHLW, the Pharmaceutical and Medical Device Agency is an independent agency that is responsible for reviewing drug and medical device applications and works with the MHLW to assess new product safety, develop comprehensive regulations, and monitor post-market safety.

The FDA and other worldwide regulatory agencies and competent authorities actively monitor compliance to local laws and regulations through review and inspection of design and manufacturing practices, record-keeping, reporting of adverse events, labeling and promotional practices. The FDA can ban certain medical devices, detain or seize adulterated or misbranded medical devices, order recall or market withdrawal of these devices and require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. The FDA may also enjoin and restrain a company for certain violations of the Food, Drug and Cosmetic Act and the Safe Medical Devices Act, pertaining to medical devices, or initiate action for criminal prosecution of such violations. Regulatory agencies and authorities in the countries where we do business can halt production in or distribution within their respective country or otherwise take action in accordance with local laws and regulations.

International sales of medical devices manufactured in the U.S. that are not approved by the FDA for use in the U.S., or that are banned or deviate from lawful performance standards, are subject to FDA export requirements. Additionally, exported devices are subject to the regulatory requirements of each country to which the device is exported.

Our quality system is designed to enable us to satisfy various international quality system regulations, including those of the U.S. FDA with respect to products sold in the U.S. All of our medical device manufacturing facilities and distribution centers are certified under the ISO 13485 quality system standard, established by the International Standards Organization (ISO) for medical devices, which includes requirements for an implemented quality system that applies to component quality, supplier control, product design and manufacturing operations.

*Healthcare Policies and Reimbursement*

Political, economic and regulatory influences around the world continue to subject the healthcare industry to potential fundamental changes that could substantially affect our results of operations. We maintain a global Government Affairs presence, headquartered in Washington, D.C., to actively monitor and advocate on myriad legislation and policies that may potentially impact us, both on a domestic and an international front. The Government Affairs office works closely with members of Congress and committee staff, the White House and administration offices, state governors, legislatures and regulatory agencies, embassies and global governments on issues affecting our business. The Government Affairs office also advocates for public policy that benefits our employees and the patients we serve, and supports the communities in which we live.

Our products are purchased principally by hospitals, physicians and other healthcare providers around the world that typically bill various third-party payers, including government programs (e.g., Medicare and Medicaid in the U.S.) and private insurance payers, for the items and services provided to their patients. Government and private sector initiatives related to limiting the

growth of healthcare costs (including price regulation), coverage and payment policies, comparative effectiveness reviews of therapies, technology assessments, price transparency and healthcare delivery and payment structure reforms, are continuing in many countries where we do business. We believe that these changes are causing the marketplace to place increased emphasis on the delivery of treatments that can reduce costs, improve efficiencies and/or increase patient access. Although we believe our products and technologies generate favorable clinical outcomes, value and cost efficiency, while also being less invasive than alternatives, the resources necessary to demonstrate value to our customers, patients, payers and other stakeholders are significant and new therapies may take significantly longer periods of time to gain widespread adoption.

Implementation of cost containment initiatives and healthcare reforms in significant markets such as the U.S., China, Australia, and other markets may limit the price of, or the level at which reimbursement is provided for, our products or procedures using our products, which in turn may make it less likely that a hospital or physician will select our products to treat patients.

*Environmental Regulation and Management*

We are subject to various environmental laws, directives and regulations both in the U.S. and abroad. Our operations involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We are focused on continuous improvement in environmental metrics with a goal of reducing pollution, minimizing depletion of natural resources and reducing our overall environmental footprint. Specifically, we are working to optimize energy and resource usage, ultimately reducing greenhouse gas emissions and waste. Refer to *Corporate Sustainability* included in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations of this Annual Report on Form 10-K for further discussion.

Human Capital

At Boston Scientific, our work is guided by core values that define our culture and empower our employees, including Caring, Diversity, Global Collaboration, High Performance, Meaningful Innovation and Winning Spirit. As of December 31, 2022, we had approximately 45,000 employees, of which approximately 56 percent were outside the U.S. We believe the collective talent of our employees and our shared corporate culture and values give us a competitive advantage.

Hiring, developing and retaining talented employees are key parts of our strategy and are critical to our success, particularly in the current environment of labor shortages and unprecedented job market conditions. We strive to do this by fostering a diverse, equitable and inclusive workplace, providing competitive pay and benefits and flexible work conditions, offering ongoing employee growth and development opportunities and cultivating a culture that prioritizes employee health, safety and well-being.

*Diversity, Equity and Inclusion*

We do our best work to advance health care when we have a diverse range of perspectives and experience on our team. Innovation thrives in a culture of engagement, inclusion and equity. The society in which we live and the customers and patients we serve are diverse and our employees at all levels of the organization must reflect this. In recent years, we have made steady progress to increase the overall representation of employees who identify as women and as African American/Black, Asian, Hispanic/Latinx, American Indian/Alaska Native, Native Hawaiian/Other Pacific Islander, and two or more races (together, multicultural talent). As of December 31, 2022, women represented 30 percent of our Board of Directors, and 49 percent of our employees. In addition, 36 percent of employees in the U.S. and Puerto Rico identified as multicultural.

We are committed to our goal of making further progress toward expanding our workforce diversity. In 2020, we set measurable Diversity, Equity & Inclusion (DE&I) goals with our "3UP by 2023" initiative, which included aspirations of a three percentage point increase in representation of both women and multicultural talent at the supervisor and manager level to 43 percent and 23 percent, respectively, by December 31, 2022. As of December 31, 2022, 42.6 percent of management roles were held by women and, within the U.S and Puerto Rico, 22.6 percent were held by multicultural employees. While we are making progress, our work is far from over. We are committed to intentional action to drive meaningful change. We listen to our employees and use that feedback to complement and expand our existing DE&I programs to emphasize initiatives aimed at developing our pipeline of talent and fostering a psychologically safe and inclusive workplace for all. Additionally, our Executive Committee and our Board of Directors have oversight of employee diversity metrics and hiring trends. As evidence of our commitment to expand DE&I, in 2021, we introduced an ESG scorecard, including DE&I metrics, to our Annual Bonus Plan.

In addition, our ten Employee Resource Groups (ERGs) are at the heart of our DE&I strategy. ERGs are voluntary, company-sponsored employee groups that foster and celebrate our diverse work environment. They provide forums for us to learn from

one another, celebrate our uniqueness and develop inclusive leadership skills. We support each ERG by designating global and local executive sponsors and providing financial resources. Our ERG chapters around the world collaborate across the business at all levels and are powerful voices for change in the company.

Additionally, our approach to supplier selection involves building DE&I throughout the Boston Scientific supplier network. We are committed to the increased and sustained support of diverse businesses that share our dedication to improving the quality of patient care. As part of our strategy to combat racism, we have taken steps to further expand the number of Black-owned enterprises that provide supply chain services for our business in the U.S., and are also supporting small and diverse vendors by shortening our standard payment terms.

*Compensation and Benefits*

We offer competitive, performance-based compensation programs, recognizing that employee well-being, safety, culture, engagement and recognition are all critical to a healthy work environment and productive workforce. We offer programs that acknowledge, respect and support an individual's life and work choices. Our holistic programs are guided by overall workforce health, focusing on physical, financial and emotional well-being as well as a healthy work environment. We believe that investing in employee well-being leads to improved performance for the individual and the organization.

As part of our broader rewards portfolio, we offer competitive pay and benefits that are flexible and affordable to meet the individual needs of our employees. In addition to cash-based salaries, our rewards portfolio includes cash bonus programs, sales incentives, stock awards, recognition awards, health insurance, paid time off and family leave, retirement savings plans, childcare and Employee Assistance Programs that encourage overall well-being, including help with finances, inclusive family planning and support, elder/child care, legal support and mental health resources.

Equal pay for equal work is rooted in our values and foundational to fostering an inclusive environment. Pay equity is an important part of our long-standing global compensation planning practices. Sustaining pay equity requires constant measurement and attention, so we regularly conduct comprehensive audits, internal and external analyses and company-wide benchmarking of salaries to identify and eliminate disparities. In addition, we periodically contract with an independent, third party to assess pay equity across all positions. Our most recent pay equity study, completed in 2021, reported no statistically significant pay disparity for approximately 99 percent of our employees across gender globally and for multicultural talent in the U.S. and Puerto Rico. We continue to educate and train our people, update policies and expand benefits to decrease bias, increase gender and racial representation within our organization, and foster a culture where all employees feel valued and included.

*Employee Health and Safety*

We take a global approach to prioritizing and monitoring employee health and safety and we strive to foster a safety-oriented culture in all of our offices and facilities. We set health and safety goals which measure the number of injuries per 100 employees for the global organization. Our Employee Health & Safety Global and Regional Councils review performance monthly to discuss trends and risks, as well as opportunities for improvement. We have obtained ISO 45001:2018 Occupational Health and Safety Management System at eight of our key global locations. This is a globally recognized standard for employee Occupational Health and Safety, established by the International Standards Organization, which provides a voluntary framework to identify key occupational health and safety aspects associated with our business helping to deliver continuous improvement. We have established a company-wide safety goal of 0.25 or fewer injuries per 100 employees by 2030, cutting our year-over-year incident rate by approximately 50 percent from a base year of 2019. As of December 31, 2022, we have achieved a safety level of 0.28 per 100 employees.

*Employee Growth and Development*

Developing our people professionally is one of the most important things we do. We have robust succession planning to ensure our future leaders are ready to assume roles as they become available. At every level of the company, employees have access to training and tools they can use to advance their skills and expertise and create greater possibilities for their careers. We offer professional and technical courses, including on-the-job training, skills-based learning, mentoring opportunities and leadership development programs for high-potential employees.

*Employee Engagement*

We seek ongoing feedback from our employees to better understand what we are doing well and, conversely, how we can improve their experience. In addition to encouraging ongoing communication and feedback between employees and their

managers, we conduct periodic employee engagement surveys to ensure all employees have an opportunity to share their insights and we take appropriate action in response. As evidence of our commitment to foster employee engagement, we include these metrics within the ESG scorecard that forms part of our Annual Bonus Plan.

Community Outreach

We are united by a goal to make a difference in the lives of the over 33 million patients we serve annually. The Boston Scientific Caring value guides us in the work we do each day including how we invest in the well-being of communities. We work to advance possibilities in our three focus areas of health, STEM education and community. Our efforts evolve frequently as do the pressing needs of our communities. In 2022, we focused on supporting Ukrainian refugees, providing aid to those impacted by natural disasters and addressing the basic needs of underserved populations in communities where we live and work. In February 2023, we provided donations to charitable organizations providing earthquake relief efforts in Türkiye and Syria, including overnight stays, meals, hygiene items and critical emergency supplies.

Our global community programs empowered employees to participate in and influence the way we care for local communities through volunteerism and personal donations. Many employees chose to support their communities through use of the Employee Matching Gifts program, which was doubled in 2022 on Giving Tuesday, the global day of giving that highlights the importance of supporting local communities around the world during the holiday season. Through employee contributions and the Boston Scientific match, a total of nearly $2 million was donated in 2022. In February 2023, we launched an additional match campaign through our Employee Matching Gifts Program for aid to Türkiye and Syria and are also providing volunteer opportunities for our employees based in Türkiye to give back to their local communities.

We have also collaborated with non-profit community organizations to decrease health disparities and reduce the risk for chronic disease for the underserved by increasing access to healthcare and screenings. Within many of the communities in which we operate, we have launched and funded a multi-year program to combat racism, inequity and injustice focused on five pillars: community, economic empowerment, education, healthcare disparities and government policies. We also continue our long-term Close the Gap initiative, which focuses on raising awareness and empowering healthcare providers to reach more patients of color, fight longstanding inequities, and address barriers to care. Through Close the Gap, hospitals and health systems are provided with zip code level data that highlight the disease prevalence and disparities occurring in their communities. The information, along with our health equity resources, allows health care administrators and providers to focus on improving care to underserved populations within their communities.

We are also passionate about inspiring young learners to see themselves in a Science, Technology, Engineering and Math (STEM) roles in the future. Employees on our global STEM teams worldwide work with underrepresented K-12 students to share their passion for STEM by providing interactive product demos, development programs, and hands-on activities for young learners in their communities.

Seasonality

Our net sales are influenced by many factors, including product launches, acquisitions, regulatory and reimbursement approvals, patient, physician and employee holiday schedules and other macro-economic conditions. While our consolidated net sales do not reflect any significant degree of seasonality, customer purchases of our medical devices have historically been lower in the first and third quarters of the year.

Available Information

Copies of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act), are available free of charge on our website (www.bostonscientific.com) as soon as reasonably practicable after we electronically file the material with or furnish it to the U.S. Securities and Exchange Commission (SEC). Additionally, the SEC maintains an internet site (www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. Printed copies of these posted materials are also available free of charge to stockholders who request them in writing from Investor Relations, 300 Boston Scientific Way, Marlborough, MA 01752-1234. Information on our website or linked to our website is not incorporated by reference into this Annual Report on Form 10-K.

Safe Harbor for Forward-Looking Statements

Certain statements that we may make from time to time, including statements contained in this Annual Report on Form 10-K and information incorporated by reference into this Annual Report on Form 10-K, constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend," "aim," "goal," "target," "continue," "hope," "may" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements.

The forward-looking statements in this Annual Report on Form 10-K are based on certain risks and uncertainties, including the risk factors described in Item 1A under the heading "Risk Factors" and the specific risk factors discussed below and in connection with forward-looking statements throughout this Annual Report on Form 10-K, which could cause actual results to vary materially from the expectations and projections expressed or implied by our forward-looking statements. These risks and uncertainties, in some cases, have affected and in the future could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this Annual Report on Form 10-K. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements. Risks and uncertainties that may cause such differences include, among other things: future U.S. and global economic, political, competitive, reimbursement and regulatory conditions; manufacturing, distribution and supply chain disruptions and cost increases; disruptions caused by cybersecurity events; the impact of the COVID-19 pandemic on our operations and financial results; disruptions caused by extreme weather or other climate change-related events; labor shortages and increases in labor costs; new product introductions and the market acceptance of those products; markets for our products; expected pricing environment; expected procedural volumes; the closing and integration of acquisitions; clinical trial results; demographic trends; intellectual property rights; litigation; financial market conditions; the execution and effect of our restructuring program; the execution and effect of our business strategy, including our cost-savings and growth initiatives; our ability to achieve environmental, social and governance goals and commitments; and future business decisions made by us and our competitors. New risks and uncertainties may arise from time to time and are difficult to predict, including those that have emerged or may increase in significance or likelihood as a result of the COVID-19 pandemic. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A. Risk Factors contained within this Annual Report on Form 10-K filed with the SEC, which we may update in Part II, Item 1A. Risk Factors in subsequent Quarterly Reports on Form 10-Q that we will file hereafter. We disclaim any intention or obligation to publicly update or revise any forward-looking statement to reflect any change in our expectations or in events, conditions, or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements. This cautionary statement is applicable to all forward-looking statements contained in this Annual Report on Form 10-K.

The following are some of the important risk factors that could cause our actual results to differ materially from our expectations in any forward-looking statements. For further discussion of these and other risk factors, see Item 1A. Risk Factors.

*Our Businesses*

- The impact of the COVID-19 pandemic and economic conditions created in part by the pandemic on worldwide economies, financial markets, manufacturing and distribution systems, including disruption in the manufacture or supply of certain components, materials or products, and business operations,

- Labor shortages and the impact of inflation on the cost of raw materials and direct labor,

- Risks associated with challenging or uncertain domestic and international economic conditions, including those related to rising interest rates, inflation, currency devaluations or economies entering into periods of recession,

- The impact of natural disasters, climate change, additional future public health crises and other catastrophic events on our ability to manufacture, distribute and sell our products,

- The impact of competitive offerings, value-based procurement practices, government-imposed payback provisions and changes in reimbursement practices and policies on average selling prices for our products,

- The ongoing impact on our business of physician alignment to hospitals, governmental investigations and audits of hospitals and other market and economic conditions on the overall number of procedures performed,

- The performance of, and physician and patient confidence in, our products and technologies or those of our competitors,

- The impact and outcome of ongoing and future clinical trials and market studies undertaken by us, our competitors or other third parties or perceived product performance of our or our competitors' products,

- Variations in clinical results, reliability or product performance of our and our competitors' products,

- Our ability to acquire or develop, launch and supply new or next-generation products and technologies worldwide and in line with our commercialization strategies in a timely and successful manner and with respect to our recent acquisitions,

- The effect of consolidation and competition in the markets in which we do business or plan to do business,

- Our ability to achieve our projected level or mix of product sales, as some of our products are more profitable than others,

- Our ability to attract and retain talent, including key personnel associated with recent acquisitions, and to maintain our robust corporate culture,

- The impact of enhanced requirements to obtain and maintain regulatory approval in the U.S. and around the world, including EU MDR and the associated timing and cost of product approval,

- The impact of increased pressure on the availability and rate of third-party reimbursement for our products and procedures in the U.S. and around the world, including with respect to the timing and costs of creating and expanding markets for new products and technologies,

- The issuance of new or revised accounting standards by the Financial Accounting Standards Board or the Securities and Exchange Commission, and

- The impact of potential goodwill and intangible asset impairment charges on our results of operations.

*Regulatory Compliance, Litigation and Data Protection*

- The impact of healthcare policy changes and legislative or regulatory efforts in the U.S., the EU and around the world to modify product approval or reimbursement processes, including a trend toward demonstrating clinical outcomes, comparative effectiveness and cost efficiency, as well as the impact of other healthcare reform legislation,

- Risks associated with our regulatory compliance and quality systems and activities in the U.S., the EU and around the world, including meeting regulatory standards applicable to manufacturing and quality processes,

- The effect of global legal, regulatory or market responses to climate change, including increased compliance burdens and costs to meet regulatory obligations,

- Our ability to minimize or avoid future field actions or FDA warning letters relating to our products and processes and the ongoing inherent risk of potential physician advisories related to our or our competitors' products,

- The impact of increased scrutiny of and heightened global regulatory enforcement facing the medical device industry arising from political and regulatory changes, economic pressures or otherwise, including under U.S. Anti-Kickback Statute, U.S. False Claims Act and similar laws in other jurisdictions, U.S. Foreign Corrupt Practices Act (FCPA) and similar laws in other jurisdictions, and U.S. and foreign export control, trade embargo and customs laws,

- Costs and risks associated with current and future asserted litigation,

- The effect of our litigation and risk management practices, including self-insurance and compliance activities on our loss contingencies, legal provisions and cash flows,

**Attachment C**

**Corporation Information**

Boston Scientific Corporation
(a publicly traded company)

**Corporate Officers:**

Michael F. Mahoney
*Chairman and Chief Executive Officer*

Daniel J. Brennan
*Executive Vice President, Chief Financial Officer*

J. Bradley Sorenson
*Executive Vice President, Global Operations*

Vance R. Brown
*Senior Vice President, General Counsel and Corporate Secretary*

**Directors:**

Nelda J. Connors
Charles J. Dockendorf
Yoshiaki Fujimori
Edward J. Ludwig
Michael F. Mahoney
David Roux
John E. Sununu
David S. Wichmann
Ellen M. Zane

**Top four Shareholders:**

| | | | |
|---|---|---|---|
| Name: | BlackRock, Inc. | Ownership %: | 9.59 |
| Name: | The Vanguard Group, Inc. | Ownership %: | 8.26 |
| Name: | FMR LLC | Ownership %: | 7.32 |
| Name: | Massachusetts Financial Services Company | Ownership %: | 5.74 |

# Delaware

The First State



I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THAT "BOSTON SCIENTIFIC CORPORATION" IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE NOT HAVING BEEN CANCELLED OR DISSOLVED SO FAR AS THE RECORDS OF THIS OFFICE SHOW AND IS DULY AUTHORIZED TO TRANSACT BUSINESS.

THE FOLLOWING DOCUMENTS HAVE BEEN FILED:

CERTIFICATE OF INCORPORATION, FILED THE TWENTY-SECOND DAY OF JUNE, A.D. 1979, AT 10 O`CLOCK A.M.

CERTIFICATE OF AMENDMENT, FILED THE THIRTEENTH DAY OF OCTOBER, A.D. 1982, AT 2 O`CLOCK P.M.

CERTIFICATE OF AMENDMENT, FILED THE FIFTH DAY OF NOVEMBER, A.D. 1982, AT 3 O`CLOCK P.M.

CERTIFICATE OF OWNERSHIP, FILED THE TWENTY-SEVENTH DAY OF DECEMBER, A.D. 1988, AT 9 O`CLOCK A.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE EFFECTIVE DATE OF THE AFORESAID CERTIFICATE OF OWNERSHIP IS THE FIRST DAY OF JANUARY, A.D. 1989.

Jeffrey W. Bullock, Secretary of State

874815 8310

SR# 20231869197

Authentication: 203294391

Date: 05-08-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

# Delaware

The First State



*RESTATED CERTIFICATE, FILED THE THIRTY-FIRST DAY OF MARCH, A.D. 1992, AT 2:15 O`CLOCK P.M.*

*RESTATED CERTIFICATE, FILED THE EIGHTEENTH DAY OF MARCH, A.D. 1994, AT 10 O`CLOCK A.M.*

*CERTIFICATE OF AMENDMENT, FILED THE TWENTY-FOURTH DAY OF FEBRUARY, A.D. 1995, AT 4:30 O`CLOCK P.M.*

*CERTIFICATE OF CHANGE OF REGISTERED AGENT, FILED THE TWENTY-FIFTH DAY OF AUGUST, A.D. 1998, AT 9 O`CLOCK A.M.*

*CERTIFICATE OF AMENDMENT, FILED THE FOURTH DAY OF NOVEMBER, A.D. 1998, AT 9 O`CLOCK A.M.*

*CERTIFICATE OF AMENDMENT, FILED THE SIXTH DAY OF OCTOBER, A.D. 2003, AT 1:32 O`CLOCK P.M.*

*CERTIFICATE OF OWNERSHIP, FILED THE TWENTIETH DAY OF DECEMBER, A.D. 2005, AT 1:20 O`CLOCK P.M.*

*AND I DO HEREBY FURTHER CERTIFY THAT THE EFFECTIVE DATE OF THE AFORESAID CERTIFICATE OF OWNERSHIP IS THE TWENTIETH DAY OF DECEMBER, A.D. 2005 AT 11:59 O'CLOCK P.M.*

*CERTIFICATE OF AMENDMENT, FILED THE THIRTY-FIRST DAY OF MARCH, A.D. 2006, AT 2:04 O`CLOCK P.M.*







874815 8310

SR# 20231869197

Authentication: 203294391

Date: 05-08-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

| | Filing Date | Filing | Effective Date |
|---|---|---|---|
| ☐ | 7/26/2005 | Global Registered Office and/or Agent - Business Corporation (Foreign) | |
| ☐ | 08/30/2007 | Global Registered Office and/or Agent - Business Corporation (Foreign) | |
| ☐ | 01/12/2009 | Revocation - Business Corporation (Foreign) | |
| ☐ | 01/05/2010 | Reinstatement - Business Corporation (Foreign) | |
| ☐ | 2/5/2015 | Registered Office and/or Agent - Business Corporation (Foreign) | |

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# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of MDEG: Boston Scientific Corporation — MDEG License # (if applicable):

Physical Address: 10700 Xylon Ave North

City: Brooklyn Park — State: MN — Zip: 55455

Mailing Address (if different from physical address): 4100 Hamline Ave N

City: Saint Paul — State: MN — Zip: 55114

Telephone: 651-582-4000 — Website: http://www.bostonscientific.com

Licensing Company Email: STPDrugLicensing@bsci.com

**Section 2: Personal Information**

First: Daniel — Middle: James — Last: Kohout

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☒ M ☐ F ☐ X

Mailing Address: 4100 Hamline Ave N

City: Saint Paul — State: MN — Zip: 55112

Telephone: [redacted] — Email: daniel.kohout@bsci.com

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✓ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Minnesota State University, Mankato | | | 09/86-05/93 | |
| Address | | City | State | Zip |
| 3 Morris Hall | | Mankato | MN | 56001 |
| Diploma/Degree obtained, if any | | | | |
| Bachelor of Science in Chemistry, Biology and Biochemistry | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| Prior Lake High School | | | 9/82-6/86 | |
| Address | | City | State | Zip |
| 7575 150th Street W | | Savage | MN | 55378 |
| Diploma/Degree obtained, if any | | | | |
| NA | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |
| School Name | | | From - To (MM/YY – MM/YY | |
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 08/01-present | [redacted] Concord Court NW | Elk River | MN | 55330 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Boston Scientific Corporation | | | starting 1/24 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 10700 Xylon Ave North | | Brooklyn Park | MN | 55455 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 763-913-2798 | Principal Quality Engineer | | NA - under construction | |
| **Description of Duties** | | | | |
| DC Corrective Actions, Product Containment, Release Activity, Support New Product Introduction, Manage shipping discrepancies | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Boston Scientific Corporation | | | 9/19-current | |
| **Business Address** | | **City** | **State** | **Zip** |
| 4100 Hamline Ave N | | Saint Paul | MN | 55112 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 763-913-2798 | Principal Quality Engineer | | 3520 | |
| **Description of Duties** | | | | |
| DC Corrective Actions, Product Containment, Release Activity, Support New Product Introduction, Manage shipping discrepancies | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Boston Scientific Corporation | | | 5/14-9/19 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 10700 Bren Rd W | | Minnetonka | MN | 55343 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 763-913-2798 | Quality Manager | | 11040 | |
| **Description of Duties** | | | | |
| Managed and developed teams responsible for new product integration, validation, and outgoing quality level, ensured compliance to external and internal requirements, | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Boston Scientific Corporation | | | 8/06-5/14 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 1 Scimed Place/5905 Nathan Ln N | | Maple Grove/Plymouth | MN | 55311 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 763-913-2798 | Principal Design Quality Engineer/Quality Manager | | 18080 | |
| **Description of Duties** | | | | |
| • Created protocols and reports for product to be distribution tested, age tested and functionally tested | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

Continue on next page if additional space is needed.

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state? | | ✓ |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline. | | ✓ |

**Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Daniel Kohout, **certify that as the MDEG Administrator for**

Boston Scientific Corporation,

**that I (initial that you have read and meet the following requirements):**

1. DK Have a high school diploma or its equivalent;
2. DK Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. DK Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. DK Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Daniel Kohout
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

26-JUN-2023
Date

| Board Use Only | Date Received: 6-29-23 |
|---|---|

# MEMORANDUM OF INSURANCE

DATE: 26-Jun-2023

This Memorandum is issued as a matter of information only to authorized viewers for their internal use only and confers no rights upon any viewer of this Memorandum. This Memorandum does not amend, extend or alter the coverage described below. This Memorandum may only be copied, printed and distributed within an authorized viewer and may only be used and viewed by an authorized viewer for its internal use. Any other use, duplication or distribution of this Memorandum without the consent of Marsh is prohibited. "Authorized viewer" shall mean an entity or person which is authorized by the insured named herein to access this Memorandum via https://marshdigital.marsh.com/marshconnect/viewMOI.action?clientId=3535972. The information contained herein is as of the date referred to above. Marsh shall be under no obligation to update such information.

| PRODUCER | COMPANIES AFFORDING COVERAGE |
|---|---|
| Marsh USA LLC ("Marsh") | Co. A Liberty Mutual Fire Insurance Company |
| INSURED<br>Boston Scientific Corporation<br>300 Boston Scientific Way<br>Marlborough<br>Massachusetts 01752<br>United States | Co. B LM Insurance Corporation |
| | Co. C Illinois Union Insurance Company |
| | Co. D American Guarantee and Liability Insurance Company |
| | Co. E North American Capacity Insurance Co. |
| | Co. F |

**COVERAGES**

THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS MEMORANDUM MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS

| CO LTR | TYPE OF INSURANCE | POLICY NUMBER | POLICY EFFECTIVE DATE | POLICY EXPIRATION DATE | LIMITS (LIMITS IN USD UNLESS OTHERWISE INDICATED) | |
|---|---|---|---|---|---|---|
| A | GENERAL LIABILITY<br>Commercial General Liability<br>Occurrence | TB2-611-004519-073 | 29-Jun-2023 | 29-Jun-2024 | GENERAL AGGREGATE | USD 4,000,000 |
| | | | | | PRODUCTS - COMP/OP AGG | EXCLUDED |
| | | | | | PERSONAL AND ADV INJURY | USD 2,000,000 |
| | | | | | EACH OCCURRENCE | USD 2,000,000 |
| | | | | | FIRE DAMAGE (ANY ONE FIRE) | USD 250,000 |
| | | | | | MED EXP (ANY ONE PERSON) | USD 10,000 |
| A | AUTOMOBILE LIABILITY<br>Any Auto | AS2-611-004519-013 | 29-Jun-2023 | 29-Jun-2024 | COMBINED SINGLE LIMIT | USD 1,000,000 |
| | | | | | BODILY INJURY (PER PERSON) | |
| | | | | | BODILY INJURY (PER ACCIDENT) | |
| | | | | | PROPERTY DAMAGE | |
| D | EXCESS LIABILITY<br>Other than Umbrella Form | AUC 038255406 | 29-Jun-2023 | 29-Jun-2024 | EACH OCCURENCE | 10,000,000 |
| | | | | | AGGREGATE | 10,000,000 |
| B | WORKERS COMPENSATION / EMPLOYERS LIABILITY<br>THE PROPRIETOR / PARTNERS / EXECUTIVE OFFICERS ARE Included | WA5-61D-004519-103 (AOS) | 29-Jun-2023 | 29-Jun-2024 | WORKERS COMP LIMITS | Statutory |
| B | | WC5-611-004519-113 (WI) | 29-Jun-2023 | 29-Jun-2024 | EL EACH ACCIDENT | USD 1,000,000 |
| | | | | | EL DISEASE - POLICY LIMIT | USD 1,000,000 |
| | | | | | EL DISEASE - EACH EMPLOYEE | USD 1,000,000 |
| C | Products-Completed | G21819207008 | 29-Jun-2023 | 29-Jun-2025 | Each Occurrence/Aggregate | USD 10,000,000 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | Operations | | | | | |
| | | | | | | |
| E | Cyber Risk | 5414.1 | 10-Apr-2022 | 10-Apr-2024 | Each OccurenceAggregate | USD 5,000,000 |

The Memorandum of Insurance serves solely to list insurance policies, limits and dates of coverage. Any modifications here to are not authorized.

**MEMORANDUM OF INSURANCE** | **DATE** 26-Jun-2023

This Memorandum is issued as a matter of information only to authorized viewers for their internal use only and confers no rights upon any viewer of this Memorandum. This Memorandum does not amend, extend or alter the coverage described below. This Memorandum may only be copied, printed and distributed within an authorized viewer and may only be used and viewed by an authorized viewer for its internal use. Any other use, duplication or distribution of this Memorandum without the consent of Marsh is prohibited. "Authorized viewer" shall mean an entity or person which is authorized by the insured named herein to access this Memorandum via https://marshdigital.marsh.com/marshconnect/viewMOI.action?clientId=3535972. The information contained herein is as of the date referred to above. Marsh shall be under no obligation to update such information.

| PRODUCER | INSURED |
|---|---|
| Marsh USA LLC<br>("Marsh") | Boston Scientific Corporation<br>300 Boston Scientific Way<br>Marlborough<br>Massachusetts 01752<br>United States |

**ADDITIONAL INFORMATION**

Products-Completed Operations coverage is provided on a Claims-Made basis excess of a $1,000,000 self insured retention.

Cyber Risk Retention: USD 1,000,000

The Memorandum of Insurance serves solely to list insurance policies, limits and dates of coverage. Any modifications hereto are not authorized.

**Attachment E**

**Employee List**

Michael Morris
*Materials Distribution Manager I*

Scott Link
*Senior Materials Supervisor*

Daniel Kohout
*Principal Quality Engineer*

# 4EE

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

**Non-Refundable $1,000 Fee**

Rev (08/17/2022)

| **Where is the facility located?** | | ☐ Nevada ☒ Out-of-State |
|---|---|---|
| **Type of Application (check applicable box)** | | **Wholesaler Business Type (check applicable box)** |
| ☐ New Wholesaler<br>☒ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH 03202 | ☒ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: Chemocentryx Inc.

Physical Address: 835 Industrial Road, Suite 600

City: San Carlos State: CA Zip: 94070

Mailing Address (if different from physical address): 835 Industrial Rd. Ste 600

City: San Carlos State: CA Zip: 94070

Telephone: 650-210-2900 Website: www.chemocentryx.com

Name of Designated Representative (DR): Alok Bhatt

Licensing Company Email: nschippe@amgen.com DR Email: abhatt@chemocentryx.com

| **Entities the Wholesaler will Serve (✓ all applicable)** | **Products to be Handled or Wholesaled (✓ all applicable)** | **Type of Wholesaling (✓ all applicable)** |
|---|---|---|
| ☐ Pharmacies | ☒ Dangerous Drugs | ☐ Manufacturer |
| ☐ Practitioners | ☐ Controlled Substances | ☐ Repacker |
| ☐ Hospitals | ☐ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ☐ Wholesalers | ☐ Others: | ☐ Warehouse |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ☒ Others: Specialty Distributors, Specialty Pharmacies | | ☒ Others: Virtual Manufacturer |

| **Section 2: History of Company** | **Yes** | **No** |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | x |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | x |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | x |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | x |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | x |

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

**Section 4: Publicly Traded Corporation**

State of Incorporation: DE

Parent Company (if any): Amgen

Corporation Name: ChemoCentryx, Inc.

Mailing Address: 835 Industrial Rd. Ste 600

City: San Carlos State: CA Zip: 94070

Telephone: 650-210-2900 Email: nschippe@amgen.com

Contact Person Name: Somnath Chattopadhyay

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: AMGN |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

**Section 6: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

**Section 7: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

Date

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | x |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | | x |
| 1. Copy of FDA registration<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** | | ✓ | | |
| • **List of all partners and their percent ownership.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Chemocentryx Inc.
Facility Name

Somnath Chattopadhyay
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

5.18.2023
Date

| Board Use Only | Date Received: 7/3/23 | Amount: 1000-CK-18835 |
|---|---|---|

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 8-K

**CURRENT REPORT**
**Pursuant to Section 13 or 15(d) of**
**the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported)

**October 20, 2022**

# Amgen Inc.

**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-37702** | **95-3540776** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

**One Amgen Center Drive**
**Thousand Oaks**
**California**
**91320**
**(Address of principal executive offices, including zip code)**

**(805) 447-1000**
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| **Title of each class** | **Trading Symbol(s)** | **Name of each exchange on which registered** |
|---|---|---|
| **Common stock, $0.0001 par value** | **AMGN** | **The Nasdaq Stock Market LLC** |
| **2.000% Senior Notes due 2026** | **AMGN26** | **The Nasdaq Stock Market LLC** |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 7.01. Regulation FD Disclosure.**

On October 20, 2022, Amgen Inc. issued a press release announcing the completion of its previously announced acquisition of ChemoCentryx, Inc. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated into this Item 7.01 by reference.

The information contained in this Item 7.01 and Exhibit 99.1 shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), or otherwise subject to the liabilities of such section, nor will such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as may be expressly set forth by specific reference in such filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit No. | Description of Exhibit |
|---|---|
| 99.1 | Press Release, dated as of October 20, 2022 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AMGEN INC.

By: /s/ Jonathan P. Graham
Name: Jonathan P. Graham
Title: Executive Vice President, General Counsel and Secretary

Date: October 20, 2022

One Amgen Center Drive
Thousand Oaks, CA 91320-1799
Telephone 805-447-1000
www.Amgen.com

***News Release***

# AMGEN SUCCESSFULLY COMPLETES ACQUISITION OF CHEMOCENTRYX

## TAVNEOS® (avacopan), a First-in-Class Medicine for Patients With Severe Active ANCA-Associated Vasculitis, Added to Inflammation Portfolio

THOUSAND OAKS, Calif., (Oct. 20, 2022) – Amgen (NASDAQ: AMGN) today announced that it has successfully completed its previously announced acquisition of ChemoCentryx, Inc. (NASDAQ: CCXI), a biopharmaceutical company focused on orally administered therapeutics to treat autoimmune diseases, inflammatory disorders and cancer, for $52 per share in cash, representing aggregate merger consideration of approximately $3.7 billion.

"ChemoCentryx enhances Amgen's leading inflammation and nephrology portfolio and includes TAVNEOS® (avacopan), a first-in-class treatment for severe active anti-neutrophil cytoplasmic autoantibody-associated vasculitis (ANCA-associated vasculitis), an autoimmune disease for which there remains significant unmet medical need," said Robert A. Bradway, chairman and chief executive officer at Amgen. "We look forward to welcoming the dedicated professionals from ChemoCentryx who share our passion for advancing innovation that makes a difference for patients. Together, we aim to serve more patients affected by serious diseases."

The acquisition includes TAVNEOS®, an orally administered selective complement 5a receptor inhibitor that was approved by the U.S. Food and Drug Administration (FDA) in October 2021 as an adjunctive therapy for adults with severe active ANCA-associated vasculitis in addition to standard of care, which generally consists of glucocorticoids and either rituximab or cyclophosphamide immunosuppressant therapy. Beyond its approved ANCA-associated vasculitis indication, TAVNEOS® is also being studied in additional inflammatory diseases, including hidradenitis suppurativa (HS), a severe and deforming chronic dermatological condition, and complement 3 glomerulopathy (C3G), a rare genetic kidney disease.

In addition to TAVNEOS®, the acquisition adds three early-stage drug candidates that target chemoattractant receptors and other inflammatory diseases and an oral checkpoint for cancer.

**About Amgen**
Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

Amgen is one of the 30 companies that comprise the Dow Jones Industrial Average and is also part of the Nasdaq-100 index. In 2021, Amgen was named one of the 25 World's Best Workplaces™ by Fortune and Great Place to Work™ and one of the 100 most sustainable companies in the world by Barron's.

For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

**About ChemoCentryx**
ChemoCentryx is a biopharmaceutical company commercializing and developing new medications for inflammatory and autoimmune diseases and cancer. ChemoCentryx targets the chemokine and chemoattractant systems to discover, develop and commercialize orally administered therapies. In the United States, ChemoCentryx markets TAVNEOS® (avacopan), the first approved orally administered inhibitor of the complement 5a receptor as an adjunctive treatment for adult patients with severe active ANCA-associated vasculitis. TAVNEOS is also in late-stage clinical development for the treatment of severe hidradenitis suppurativa and C3 glomerulopathy (C3G). Additionally, ChemoCentryx has early-stage drug candidates that target chemoattractant receptors in other inflammatory and autoimmune diseases and in cancer. For more information about ChemoCentryx visit www.chemocentryx.com.

**About TAVNEOS® (avacopan)**
TAVNEOS (avacopan), approved by the FDA as an adjunctive treatment of ANCA-associated vasculitis, is a first-in-class, orally administered small molecule that employs a novel, highly targeted mode of action in complement-driven autoimmune and inflammatory diseases. While the precise mechanism in ANCA vasculitis has not been definitively established, TAVNEOS, by blocking the complement 5a receptor (C5aR) for the pro-inflammatory complement system fragment known as C5a on destructive inflammatory cells such as blood neutrophils, is presumed to arrest the ability of those cells to do damage in response to C5a activation, which is known to be the driver of ANCA vasculitis. TAVNEOS's selective inhibition of only the C5aR leaves the beneficial C5a pathway through the C5L2 receptor functioning normally.

ChemoCentryx is also developing TAVNEOS for the treatment of patients with C3 glomerulopathy (C3G), severe hidradenitis suppurativa (HS) and lupus nephritis (LN). The U.S. Food and Drug Administration granted TAVNEOS orphan drug designation for ANCA-associated vasculitis and C3G. The European Commission has granted orphan medicinal product designation for TAVNEOS for the treatment of two forms of ANCA-associated vasculitis: microscopic polyangiitis and granulomatosis with polyangiitis (formerly known as Wegener's granulomatosis), as well as for C3G.

**About ANCA-Associated Vasculitis**
ANCA-associated vasculitis is an umbrella term for a group of multi-system autoimmune diseases with small vessel inflammation. Inflamed vessels may rupture or become occluded giving rise to a broad array of clinical symptoms and signs related to a systemic inflammatory response which may result in profound injury and dysfunction in the kidneys, lungs and other organs. Prior to the approval of TAVNEOS, treatment for ANCA-associated vasculitis was limited to courses of non-specific immuno-suppressants (cyclophosphamide or rituximab), combined with the administration of daily glucocorticoids (steroids) for prolonged periods of time, which can be associated with significant clinical risk including death from infection.

**U.S. PRESCRIBING INFORMATION**
TAVNEOS (avacopan) is indicated as an adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids. TAVNEOS does not eliminate glucocorticoid use.

IMPORTANT SAFETY INFORMATION

Contraindications

Serious hypersensitivity to avacopan or to any of the excipients

Warning and Precautions

Hepatotoxicity: Serious cases of hepatic injury have been observed in patients taking TAVNEOS, including life-threatening events. Obtain liver test panel before initiating TAVNEOS, every 4 weeks after start of therapy for six months and as clinically indicated thereafter. Monitor patients closely for hepatic adverse reactions, and consider pausing or discontinuing treatment as clinically indicated (refer to section 5.1 of the Prescribing Information). TAVNEOS is not recommended for patients with active, untreated and/or uncontrolled chronic liver disease (e.g., chronic active hepatitis B, untreated hepatitis C, uncontrolled autoimmune hepatitis) and cirrhosis. Consider the risk and benefit before administering this drug to a patient with liver disease.

Serious Hypersensitivity Reactions: Cases of angioedema occurred in a clinical trial, including one serious event requiring hospitalization. Discontinue immediately if angioedema occurs and manage accordingly. TAVNEOS must not be re-administered unless another cause has been established.

Hepatitis B Virus (HBV) Reactivation: Hepatitis B reactivation, including life threatening hepatitis B, was observed in the clinical program. Screen patients for HBV. For patients with evidence of prior infection, consult with physicians with expertise in HBV and monitor during TAVNEOS therapy and for six months following. If patients develop HBV reactivation, immediately discontinue TAVNEOS and concomitant therapies associated with HBV reactivation, and consult with experts before resuming.

Serious Infections: Serious infections, including fatal infections, have been reported in patients receiving TAVNEOS. The most common serious infections reported in TAVNEOS group were pneumonia and urinary tract infections. Avoid use of TAVNEOS in patients with active, serious infection, including localized infections. Consider the risks and benefits before initiating TAVNEOS in patients with chronic infection, at increased risk of infection or who have been to places where certain infections are common.

Adverse Reactions

The most common adverse reactions (≥5% of patients and higher in the TAVNEOS group vs. prednisone group) were: nausea, headache, hypertension, diarrhea, vomiting, rash, fatigue, upper abdominal pain, dizziness, blood creatinine increased, and paresthesia.

Drug Interactions

Avoid coadministration of TAVNEOS with strong and moderate CYP3A4 enzyme inducers. Reduce TAVNEOS dose when co-administered with strong CYP3A4 enzyme inhibitors to 30 mg once daily. Monitor for adverse reactions and consider dose reduction of certain sensitive CYP3A4 substrates.

Please see Full Prescribing Information and Medication Guide.

**Amgen Forward-Looking Statements**
This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including any statements on the outcome, benefits and synergies of collaborations, or potential collaborations, with any other company (including BeiGene, Ltd., Kyowa-Kirin Co., Ltd., or any collaboration to manufacture therapeutic antibodies against COVID-19), the performance of Otezla® (apremilast) (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), the Five Prime Therapeutics, Inc. acquisition, the Teneobio, Inc. acquisition, or the ChemoCentryx, Inc. acquisition (including the prospective performance and outlook of ChemoCentryx's business, performance and opportunities and any potential strategic benefits, synergies or opportunities expected as a result of such acquisition), as well as estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes, effects of pandemics or other widespread health problems such as the ongoing COVID-19 pandemic on our business, and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including our most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and current reports on Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. Our results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing our products and global economic conditions. In addition, sales of our products are affected by pricing pressure, political and public scrutiny and reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. We or others could identify safety, side effects or manufacturing problems with our products, including our devices, after they are on the market. Our business may be impacted by government investigations, litigation and product liability claims. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. An outbreak of disease or similar public health threat, such as COVID-19, and the public and governmental effort to mitigate against the spread of such disease, could have a significant adverse effect on the supply of materials for our manufacturing activities, the distribution of our products, the commercialization of our product candidates, and our clinical trial operations, and any such events may have a material adverse effect on our product development, product sales, business and results of operations. We rely on collaborations with third parties for the development of some of our product candidates and for the commercialization and sales of some of our commercial products. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. The discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations. Our efforts to collaborate with or acquire other companies, products or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful. There can be no guarantee that we will be able to realize any of the strategic benefits, synergies or opportunities arising from the ChemoCentryx acquisition, and such benefits, synergies or opportunities may take longer to realize than expected. We may not be able to successfully integrate ChemoCentryx, and such integration may take longer, be more difficult or cost more than expected. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our systems and our data. Our stock price is volatile and may be affected by a number of events. Our business and operations may be negatively affected by the failure, or perceived failure, of achieving our environmental, social and governance objectives. The effects of global climate change and related natural disasters could negatively affect our business and operations. Global economic conditions may magnify certain risks that affect our business. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase our common stock. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

CONTACT: Amgen, Thousand Oaks
Jessica Akopyan, 805-440-5721 (media)
Megan Fox, 805-447-1423 (media)
Arvind Sood, 805-447-1060 (investors)




## Description of Operations

ChemoCentryx is a Virtual Manufacturer. ChemoCentryx's products are manufactured by a Contract Manufacturer and will be distributed to Specialty Distributors, Specialty Pharmacies and hospital pharmacies by their Third-Party Logistics Provider, who is licensed to ship pharmaceutical products into your state.

**Contract Manufacturer Information:**
Patheon Pharmaceuticals, Inc. manufactures ChemoCentryx's product and packages finished product. At no time does Patheon Pharmaceuticals, Inc. own the product, contract with ChemoCentryx's customers, invoice, nor sell a ChemoCentryx product. ChemoCentryx's products are not Controlled Substances.

Patheon Pharmaceuticals, Inc.
2110 E. Galbraith Rd.
Cincinnati, OH 45237
FDA Establishment Number: 1510437

**Third Party Logistics Information:**
We are using the following 3PL partner to distribute our product:

Cardinal Health 105, Inc.
501 Mason Rd. Suite 200
LaVergne, TN 37086

At no time does Patheon Pharmaceuticals, Inc. or own the product, contract with ChemoCentryx's customers, invoice, nor sell a ChemoCentryx product.

**Labeler Code:**
73556
Product: Avacopan (CCX168)

ChemoCentryx's hours of operation are 9:00 am – 5:00pm Monday through Friday.

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

# National Drug Code Directory

Current through June 29, 2023

Verified 7.5.23 BB

**You have searched Finished drug products**

**Search Results**: *'chemocentryx'*

Back to Search Page () | Search Again ()

CSV Excel

**Display** 50 **records per page** **Search for text in the table:**

| Proprietary Name | NDC Package Code | Strength | Dosage Form | Route | Appl. No. | Labeler Name | Product NDC | Nonproprietary Name | Substance Name | Product Type Name | Start Marketing Date | End Mark Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| + TAVNEOS | 73556-168-01 | 10 mg/1 | CAPSULE | ORAL | NDA214487 | ChemoCentryx, Inc. | 73556-168 | avacopan | AVACOPAN | HUMAN PRESCRIPTION DRUG | 10/18/2021 | N/A |
| + TAVNEOS | 73556-168-02 | 10 mg/1 | CAPSULE | ORAL | NDA214487 | ChemoCentryx, Inc. | 73556-168 | avacopan | AVACOPAN | HUMAN PRESCRIPTION DRUG | 10/18/2021 | N/A |

Showing 1 to 2 of 2 entries Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)

See also: Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

## Ownership Information

ChemoCentryx, Inc.
835 Industrial Rd., Suite 600
San Carlos, CA 94070
Phone: 650-210-2900
Website: Chemocentryx.com
E-mail: CCXILicensing@Amgen.com

FEIN: 94-3254365
State of Formation: DE
Date Incorporated: 11/08/1996
File Number: 2680086

ChemoCentryx is a wholly owned subsidiary of Amgen Inc.

## Officers

**Som Chattopadhyay, President, VP Global Supply Chain**
Business Address: 1 Amgen Center, Thousand Oaks, CA 91320
Business Phone: (805) 313-2605
Email: somc@amgen.com

# Delaware

The First State



*I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CHEMOCENTRYX, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTIETH DAY OF APRIL, A.D. 2023.*

*AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.*

*AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.*

Jeffrey W. Bullock, Secretary of State

2680086 8300

SR# 20231547051

Authentication: 203181323

Date: 04-20-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

# BOARD OF PHARMACY

## LICENSING DETAILS FOR: WLS 7936

**NAME:** CHEMOCENTRYX, INC.

**LICENSE TYPE:** WHOLESALER

**LICENSE STATUS:** CLEAR

**ADDRESS**

835 INDUSTRIAL RD STE 600
SAN CARLOS CA 94070
SAN MATEO COUNTY

**ISSUANCE DATE**

JUNE 4, 2021

**EXPIRATION DATE**

JUNE 1, 2024

**CURRENT DATE / TIME**

JULY 5, 2023
7:16:0 AM

## LICENSE RELATIONSHIPS

**NAME:** LIEU, JERRY

**ADDRESS NOT DISCLOSED**

**LICENSE/REGISTRATION TYPE:** REGISTERED PHARMACIST

**LICENSE NUMBER:** 70934 **PRIMARY STATUS:** CLEAR

designated representative-in-charge, and shall on the same form propose another authorized licensee to take over as the designated representative-in-charge. The proposed replacement designated representative-in-charge shall be subject to approval by the board. If disapproved, the wholesaler shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a designated representative-in-charge is approved by the board.

(g) A third-party logistics provider shall notify the board in writing, on a form designed by the board, within 30 days of the date when a responsible manager ceases to act as the responsible manager, and shall on the same form propose another designated representative-3PL to take over as the responsible manager. The proposed replacement responsible manager shall be subject to approval by the board. If disapproved, the third-party logistics provider shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a responsible manager is approved by the board.

(h) A drug manufacturer premises licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.

(i) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be required in an amount established by the board as specified in subdivision (f) of Section 4400. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's

designated representative or pharmacist proposed to serve as the designated representative-in-charge. The proposed designated representative-in-charge shall be subject to approval by the board. The board shall not issue or renew a wholesaler license without identification of an approved designated representative-in-charge for the wholesaler. The designated representative-in-charge shall maintain an active license as a designated representative with the board at all times during which he or she is designated as the designated representative-in-charge. A wholesaler that only acts as a reverse distributor may identify and allow a designated representative-reverse distributor to perform in this capacity. That individual shall maintain an active license as a designated representative-reverse distributor.

(e) Each place of business of a third-party logistics provider shall be supervised and managed by a responsible manager. The responsible manager shall be responsible for the compliance of the place of business with state and federal laws governing third-party logistics providers and with the third-party logistics provider's customer specifications, except where the customer's specifications conflict with state or federal laws. As part of its initial application for a license, and for each renewal, each third-party logistics provider shall, on a form designated by the board, provide identifying information and the California license number for a designated representative-3PL proposed to serve as the responsible manager. The proposed responsible manager shall be subject to approval by the board. The board shall not issue or renew a third-party logistics provider license without identification of an approved responsible manager for the third-party logistics provider. The responsible manager shall maintain an active license as a designated representative-3PL with the board at all times during which he or she is designated as the responsible manager.

(f) A wholesaler shall notify the board in writing, on a form designed by the board, within 30 days of the date when a designated representative-in-charge ceases to act as the

(2) A wholesaler and a third-party logistics provider under common ownership may be licensed at the same place of business provided that all of the following requirements are satisfied:

(A) The wholesaler and the third-party logistics provider each separately maintain the records required under Section 4081.

(B) Dangerous drugs and dangerous devices owned by the wholesaler are not commingled with the dangerous drugs and dangerous devices handled by the third-party logistics provider.

(C) Any individual acting as a designated representative for the wholesaler is not concurrently acting as a designated representative-3PL on behalf of the third-party logistics provider. Nothing in this subparagraph shall be construed to prohibit an individual from concurrently holding a license to act as a designated representative and to act as a designated representative-3PL.

(D) The wholesaler has its own designated representative-in-charge responsible for the operations of the wholesaler and the third-party logistics provider has its own responsible manager responsible for the operations of the third-party logistics provider. The same individual shall not concurrently serve as the responsible manager and the designated representative-in-charge for a wholesaler and a third-party logistics provider licensed at the same place of business.

(E) The third-party logistics provider does not handle the prescription drugs or prescription devices owned by a prescriber.

(F) The third-party logistics provider is not a reverse third-party logistics provider.

(G) The wholesaler is not acting as a reverse distributor.

(d) Every wholesaler shall be supervised or managed by a designated representative-in-charge. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. As part of its initial application for a license, and for each renewal, each wholesaler shall, on a form designed by the board, provide identifying information and the California license number for a

**4155. Corporate Form Not Required**

Nothing in this article shall be construed as requiring the applicant or holder of a pharmacy permit pursuant to Section 4110 to be a pharmacy corporation.

**4156. Unprofessional Conduct by Corporation**

A pharmacy corporation shall not do, or fail to do, any act where doing or failing to do the act would constitute unprofessional conduct under any statute or regulation. In the conduct of its practice, a pharmacy corporation shall observe and be bound by the laws and regulations that apply to a person licensed under this chapter.

## Article 11. Wholesalers, Third-Party Logistics Providers and Manufacturers

**4160. Wholesaler or Third-Party Logistics Provider: License Required**

(a) A person shall not act as a wholesaler or third-party logistics provider of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.

(c) (1) A separate license shall be required for each place of business owned or operated by a wholesaler or third-party logistics provider. Each place of business may only be issued a single license by the board, except as provided in paragraph (2). Each license shall be renewed annually and shall not be transferable. At all times during which a place of business is open for business, at least one designated representative, in the case of a wholesaler, or designated representative-3PL in the case of a third-party logistics provider, shall be present. A wholesaler that only acts as a reverse distributor may use either a designated representative or a designated representative-reverse distributor to fulfill this requirement.

1302

Employee List

| Last name, First name |
| --- |
| Adenle, Adebisi |
| Alam, Md Shaheedul |
| Alnagem, Susan |
| Arungwa, Perpetua |
| Athey, Kelly |
| Avigliano, Michael |
| Bautista, Manuel |
| Bernstein, Robert |
| Bhatt, Alok |
| Bickel, Neill |
| Blecha, Kathy |
| Bleibaum, Janice |
| Bonnemaison, Lucia |
| Brittain, Donovan |
| Butler, Eric |
| Butt, Tausif |
| Calara, Edgar |
| Campbell, James |
| Campione, Jill |
| Camporeale, Camille |
| Cappel, Markus |
| Casey, Sharon |
| Celestin, Clovis |
| Cerda, Rene |
| Chan, Cherine |
| Chao, Benson |
| Chen, Hang |
| Chen, Michael |
| Cheng, Mark |
| Clancy, Stacyann |
| Cogan, Thomas |
| Collins, Lisa Marie |
| Costello, Danielle |
| Csont, Brennen |
| Dang, Ton |
| Davis, Arleen |
| De La Rosa, Alex |
| deGoma, Emil |
| Dunlap, Carolyn |
| Easterday, Ashton |
| Ebsworth, Karen |
| El-Miaari, Otra |
| Enriquez, Horacio |
| Ertl, Linda |

Fan, Pingchen
Ferrari, Steven
Fitt, Virginia
Flitter, Kevin
Freeland, Ryan
Friedman, Samantha
Gagrat, Eric
Gaspar, Brigido Avila
Ghosh, Sangita
Girardeau, Maurice
Gleason, Lynn
Goli, Surender
Graves, Jeffrey
Groome, Kimberly
Gui, Ziqi
Gupta, Suprit
Harland, Aubrie
Harman, Kristen
Hatch, Tucker
Heisler, Heidi
Hensley, Suzanne
Herndon, Robin
Hughes, Karina
Ivanovic, Igor
Jain, Rita
Johnson, James
Kanagala, Suhasini
Kanaya, Susan
Kavalakatt, Pauly
Kedia, Priyanka
Kenady, Michael
Kim, Tara
Knoll, Jim
Koebbeman, Pamela
Kokubun, Sharon
Krasinski, Antoni
Kurse, Gopalkrishna
LaCivita, Eric
LaFave, Mark
LaLone, Tammy
Lange, Christopher
Larios, Norma
Lau, Fiona
Lawson, Lauryn
Le, Jennifer
Lee, Samuel

Lee, Tommy
Leetch, Kari
Li, Shijie
Lieu, Jerry
Liu, Eric
Liu, Xiaoli
Lowe, Amanda
Lui, Rebecca
Luttrell, Alexis
MacDonald, David
Malathong, Viengkham
Malone, Susan
Marshall, Daniel
Mayrand, Kurt
McRee, Courtney
Mehta, Jayantkumar
Mehta, Nikhil
Mendoza, Felipe
Miao, Shichang
Miao, Zhenhua
Michna, Melissa
Monroy, Charito
Monzon, Jennifer
Nelson, John
O'Carroll, Diem
Ooi, Liang
Owens, Bridget
Palmisano, Larry
Paperiello, Beverly
Parsons, Reginald
Patel, Shruti
Pham, An
Phung, Hong
Pineiro, John
Polit, Jose
Pollock-Dove, Crystal
Prabhakaran, Seema
Realin, Mary Ann
Richards, Kari
Rivera, Leonardo
Roberts-Houghton, Traci
Rodriguez, Vermali
Roth, Howard
Rountree, Lorraine
Ruppert, Erica Jon
Rushton, Kellie

Saechao, Kae
Sampat, Hamir
Sarabia, Rafael
Scamp, Ryan
Schall, Thomas
Schantz, Robin
Scheibler, Patrick
Schippers, Neil
Seybold, Darrin
Sheynis-Vega, Irene
Slattery, William
Snyder, Gary
Solano, Shayne
Staff, Sean
Su, Fay
Sullivan, Kathleen
Takayoshi-Berta, Sandy
Thakker, Mamta
Thompson Jr., Robert
Thompson, Victoria
Torres, Lory
Trimpe, Darcy
Truong, Ruth
Tucker, Tracy
Underwood, Gary
Vanover, Charlene
Villagomez, Fabiola
Villano, Matthew
Villegas, Robert
Von Hennigs, Irene
Waller, Carolyn
Wang, Yu
Watkins, Craig
Wishes, Jean
Wolfgang, Brett
Yandoc, Anna Lissa
Yang, Ju
Yao, Chih-Chieh
Young, Kimberly
Yue, Huibin
Zaksek, John
Zeng, Yibin
Zhang, Penglie
Zhang, Wen
Zhang, Yan Ling
Zhao, Bin

# 4FF

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application
## Non-Refundable $1,000 Fee

Rev (08/17/2022)

| Where is the facility located? | ☐ Nevada ☒ Out-of-State |
|---|---|

| | | |
|---|---|---|
| ☒ New Wholesaler | * If making a change, provide current license number: | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) |
| ☐ Ownership Change* | | ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) |
| ☐ Name Change* | | ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) |
| ☐ Location Change* (in-state only) | WH _____ | ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

Facility Name: Fountain Medical Supplies Inc.

Physical Address: 1223 S. 1840 W.

City: Orem State: Utah Zip: 84058

Mailing Address (if different from physical address): same as above

City: _____ State: _____ Zip: _____

Telephone: _____ Website: www.fountainmedicalsupplies.com

Name of Designated Representative (DR): David Harrington

Licensing Company Email: info@fountainmedicalsupplies.com DR Email: david@fountainmedicalsupplies.com

| | | |
|---|---|---|
| ☒ Pharmacies | ☐ Dangerous Drugs | ☐ Manufacturer |
| ☒ Practitioners | ☐ Controlled Substances | ☐ Repacker |
| ☐ Hospitals | ☒ [a] Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ☒ Wholesalers | ☐ Others: | ☒ Warehouse |
| ☐ Veterinarians | | ☒ Retail pharmacy wholesale distributor |
| ☒ Others: clinics | | ☐ Others: |

| | | |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | X |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | X |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | X |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | X |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | X |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

N/A

Original Signature (electronic, copies or stamps not accepted)

8/8/23
Date

Name: Armas
Address: 303 W. Main St. STE #300 City: Freehold State: NJ Zip: 07728

Name: Fosun-pharma
Address: 104 Carnegie Center Drive STE #204 City: Princeton State: NJ Zip: 08540

Name: Merit Pharmaceuticals
Address: 2611 N. San Fernando Road City: Los Angeles State: CA Zip: 90065

Name: McKesson
Address: 1900 S 4490 W City: SLC State: UT Zip: 84104

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

State of Incorporation/Organization: Utah
Parent Company (if any): N/A
Corporation/Organization Name: Fountain Medical Supplies Inc
Mailing Address: 1223 S. 1840 W.
City: Orem State: Utah Zip: 84058
Telephone: 801-980-9022 Email: info@fountainmedicalsupplies.com
Contact Person Name: Andrea Harrington

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

| | | |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | X |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | | X |
| 1. Copy of FDA registration<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |

| | | | | |
|---|---|---|---|---|
| • **List of all Officers and Directors.** | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** | | ✓ | | |
| • **List of all partners and their percent ownership.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). | ✓ | ✓ | ✓ | ✓ |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Fountain Medical Supplies Inc.

Facility Name

David Harrington

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

8/8/23

Date

| Board Use Only | Date Received: _____ Amount: _____ |
|---|---|

## Fountain Medical Supplies Inc.

## Organizational Chart





**Utah Department of Commerce**
**Division of Corporations & Commercial Code**
**160 East 300 South, 2nd Floor, PO Box 146705**
**Salt Lake City, UT 84114-6705**
**Service Center: (801) 530-4849**
**Toll Free: (877) 526-3994 Utah Residents**
**Fax: (801) 530-6438**
**Web Site: http://www.commerce.utah.gov**

11/29/2022
12844614-014211292022-458666

# CERTIFICATE OF EXISTENCE

| | |
|---|---|
| **Registration Number:** | 12844614-0142 |
| **Business Name:** | FOUNTAIN MEDICAL SUPPLIES INC. |
| **Registered Date:** | May 12, 2022 |
| **Entity Type:** | Corporation - Domestic - Profit |
| **Status:** | Current |

The Division of Corporations and Commercial Code of the State of Utah, custodian of the records of business registrations, certifies that the business entity on this certificate is authorized to transact business and was duly registered under the laws of the State of Utah. The Division also certifies that this entity has paid all fees and penalties owed to this state; its most recent annual report has been filed by the Division **(unless Delinquent)**; and, that Articles of Dissolution have not been filed.

L. Veillette

Leigh Veillette
Director
Division of Corporations and Commercial Code

STATE OF UTAH
DEPARTMENT OF COMMERCE
ACTIVE LICENSE

**Fountain Medical Supplies Inc**

EFFECTIVE 11/10/2022
EXPIRATION 05/10/2023

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

13111948-1710 Pharmacy - Class C
13111948-8913 Dispensing Controlled Substance License

Wholesaler
Distributor

DBA: None Associated

**IMPORTANT LICENSURE REMINDERS:**

- Your license is valid until the expiration date listed on this form. Approximately 60 days prior to this expiration you will receive a renewal notice in the mail.
- Please note the address listed below. This is your public address of record for the division, and all future correspondence from the division will be mailed to this address. If you move, it is your responsibility to notify us directly of the change. Maintaining your current address with us is the easiest way to ensure continuous licensure.

FOUNTAIN MEDICAL SUPPLIES INC
1223 S 1840 W
OREM UT 84058

Please visit our web site at www.dopl.utah.gov should you have any questions in the future.

STATE OF UTAH
DEPARTMENT OF COMMERCE

**DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING**

**ACTIVE LICENSE**

EFFECTIVE DATE: **11/10/2022**

EXPIRATION DATE: **05/10/2023**

ISSUED TO: **Fountain Medical Supplies Inc**
**1223 S 1840 W**
**Orem UT 84058**

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

**13111948-1710 Pharmacy - Class C**
**13111948-8913 Dispensing Controlled Substance License**

**Wholesaler**
**Distributor**

**DBAs: None Associated**

Form #1

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206 – Reno, NV 89521 – (775) 850-1440

Send to State Board of Pharmacy for completion: A separate letter is acceptable. Do not return with application unless it has been completed by the licensing agency.

## LICENSE VERIFICATION

Name: Fountain Medical Supplies Inc

Address: 1223 S. 1840 W.

City: Orem State: Utah Zip: 84058

I hereby authorize the DOPL to furnish to the Nevada State Board of Pharmacy, the information requested below.

Signature of Applicant [signature]

THIS FORM MUST BE FORWARDED TO THE HOME STATE LICENSING AGENCY FOR COMPLETION. DO **NOT** WRITE BELOW THIS LINE

| License Number | License Status | Date License Issued | Date License Expires |
|---|---|---|---|
| 13111948-1710 | ACTIVE | 11/10/2022 | 05/10/2023 |

| Has this license been encumbered in any way? | Type of Encumbrance: (if any) |
|---|---|
| ☐ Yes ☒ No | ☐ Revoked ☐ Surrendered ☐ Limited<br>☐ Suspended ☐ Restricted ☐ Probation<br>Please attach copies of any pertinent legal documents |

USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS IF NECESSARY

| | |
|---|---|
| Has the applicant been convicted of any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? (If yes, please explain) | ☐ Yes ☒ No |
| Has the applicant furnished any false or fraudulent material in any applications made in connection with drug manufacturing or distribution? (if yes, please explain) | ☐ Yes ☒ No |
| Have any inspections of the applicant resulted in deficient ratings? (If yes, please explain) | ☐ Yes ☒ No |
| Has applicant met all licensing requirements of your state? (If no, please explain) | ☐ Yes ☒ No |

| Signature of State Official | Title | State | Date | State Seal |
|---|---|---|---|---|
| HENELE TUPOU | LICENSING SPECIALIST | UTAH | 12/06/2022 | |

DEPARTMENT OF COMMERCE · OFFICIAL OF THE STATE · NEVADA PROFESSIONAL LICENSING BOARD

SPENCER J. COX
*Governor*

DEIDRE M. HENDERSON
*Lieutenant Governor*

UTAH DEPARTMENT OF COMMERCE
Division of Professional Licensing

MARGARET W. BUSSE
*Executive Director*

MARK B. STEINAGEL
*Division Director*

# VERIFICATION OF UTAH LICENSURE

DOPL-FM-001 REV 06/08/2009
Created On: 12/6/2022
Created By: Henele Tupou

**Name of Licensee (as it appears in our records):** **Fountain Medical Supplies Inc**

**Classification of License Issued:** Pharmacy - Class C
Dispensing Controlled Substance License

**License Number**: 13111948-1710
13111948-8913

**Obtained by:** Application

**Current Status:** Active

**Original Date of Licensure:** 11/10/2022

**Expiration Date:** 05/10/2023

**NO Disciplinary Action.**

Signature: _____ Title: LICENSING SPECIALIST

Date: December 6, 2022

Henele Tupou
Licensing Specialist
801-530-6628
htupou@utah.gov

The information provided on this form is accurate and correct as of the verification creation date listed on the top of this form. Original issue dates listed, as 01/01/1910 and 01/01/1911 were unknown when the division implemented its first licensing database. If you have any questions, please contact the division.

FOUNIVT-01 JRUIZ

ACORD

# CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 1/11/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
AFS Insurance Services, Inc
PO Box 30430
Salt Lake City, UT 84130

CONTACT NAME:
PHONE (A/C, No, Ext): (801) 978-8336 FAX (A/C, No): (801) 978-8340
E-MAIL ADDRESS: afsinsurance@afstores.com

INSURER(S) AFFORDING COVERAGE NAIC #
INSURER A : Pharmacists Mutual Companies
INSURER B :
INSURER C :
INSURER D :
INSURER E :
INSURER F :

INSURED
Fountain Medical Supplies Inc.
1223 S. 1840 W.
Orem, UT 84058

COVERAGES CERTIFICATE NUMBER: REVISION NUMBER:

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

| INSR LTR | TYPE OF INSURANCE | ADDL INSD | SUBR WVD | POLICY NUMBER | POLICY EFF (MM/DD/YYYY) | POLICY EXP (MM/DD/YYYY) | LIMITS | |
|---|---|---|---|---|---|---|---|---|
| A | X COMMERCIAL GENERAL LIABILITY | | | | | | EACH OCCURRENCE $ | 1,000,000 |
| | CLAIMS-MADE X OCCUR | | | BOP0167249-01 | 9/1/2022 | 9/1/2023 | DAMAGE TO RENTED PREMISES (Ea occurrence) $ | 100,000 |
| | | | | | | | MED EXP (Any one person) $ | 5,000 |
| | | | | | | | PERSONAL & ADV INJURY $ | 1,000,000 |
| | GEN'L AGGREGATE LIMIT APPLIES PER: | | | | | | GENERAL AGGREGATE $ | 2,000,000 |
| | X POLICY PRO-JECT LOC | | | | | | PRODUCTS - COMP/OP AGG $ | 2,000,000 |
| | OTHER: | | | | | | $ | |
| A | AUTOMOBILE LIABILITY | | | | | | COMBINED SINGLE LIMIT (Ea accident) $ | 1,000,000 |
| | ANY AUTO | | | CAM0001346-01 | 9/1/2022 | 9/1/2023 | BODILY INJURY (Per person) $ | |
| | OWNED AUTOS ONLY / SCHEDULED AUTOS | | | | | | BODILY INJURY (Per accident) $ | |
| | X HIRED AUTOS ONLY / X NON-OWNED AUTOS ONLY | | | | | | PROPERTY DAMAGE (Per accident) $ | |
| | | | | | | | $ | |
| A | X UMBRELLA LIAB X OCCUR | | | | | | EACH OCCURRENCE $ | 1,000,000 |
| | EXCESS LIAB CLAIMS-MADE | | | UCL0163561-01 | 9/1/2022 | 9/1/2023 | AGGREGATE $ | 1,000,000 |
| | DED X RETENTION $ 10,000 | | | | | | $ | |
| | WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N | | | | | | PER STATUTE / OTH-ER | |
| | ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) N/A | | | | | | E.L. EACH ACCIDENT $ | |
| | If yes, describe under DESCRIPTION OF OPERATIONS below | | | | | | E.L. DISEASE - EA EMPLOYEE $ | |
| | | | | | | | E.L. DISEASE - POLICY LIMIT $ | |

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Medical supply distributor/wholesaler

CERTIFICATE HOLDER

For Evidence Only

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
John Luna

ACORD 25 (2016/03)

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The ACORD name and logo are registered marks of ACORD

# NEVADA STATE BOARD OF PHARMACY

**431 W Plumb Lane**
**Reno, NV 89509**
**(775) 850-1440**
**Fax: (775) 850-1444**

## PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. PB11562510604

Application/License No. _____

Fountain Medical Supplies Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1223 S. 1840 W. Orem, UT 84058 (Address of Applicant/Principal), as PRINCIPAL, and Philadelphia Indemnity Insurance Company (Surety Company), a corporation organized under the laws of the state of Pennsylvania (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Bala Plaza #100, Bala Cynwyd, PA 19004 - 0950 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on July 05, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

PB11562510604

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.

(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.

(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.

(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.

(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.

(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.

(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 3rd day of July, 2023.

APPLICANT/PRINCIPAL
Fountain Medical Supplies Inc.

Authorized Representative

SURETY COMPANY
Philadelphia Indemnity Insurance Company

Surety Company's Representative

Ryan Tash, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

**PHILADELPHIA INDEMNITY INSURANCE COMPANY**
One Bala Plaza, Suite 100
Bala Cynwyd, PA 19004-0950

**Power of Attorney**

NOW ALL PERSONS BY THESE PRESENTS That **PHILADELPHIA INDEMNITY INSURANCE COMPANY** (the Company), a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, does hereby constitute and appoint **John T. Page, Ryan Tash, & Susan Fournier of Surety Solutions Insurance Services, Inc.** its true and lawful Attorney-in-fact with full authority to execute on its behalf bonds, undertakings, recognizances and other contracts of indemnity and writings obligatory in the nature thereof, issued in the course of its business and to bind the Company thereby, in an amount not to exceed **$50,000,000.**

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of PHILADELPHIA INDEMNITY INSURANCE COMPANY on the 14th of November, 2016

**RESOLVED:** That the Board of Directors hereby authorizes the President or any Vice President of the Company: (1) Appoint Attorney(s) in Fact and authorize the Attorney(s) in Fact to execute on behalf of the Company bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof and to attach the seal of the Company thereto, and (2) to remove, at any time, any such Attorney-in-Fact and revoke the authority given And, be it

**FURTHER RESOLVED:** That the signatures of such officers and the seal of the Company may be affixed to any such Power of Attorney or certificate relating thereto by facsimile, and any such Power of Attorney so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking to which it is attached

IN TESTIMONY WHEREOF, PHILADELPHIA INDEMNITY INSURANCE COMPANY HAS CAUSED THIS INSTRUMENT TO BE SIGNED AND ITS CORPORATE SEALTO BE AFFIXED BY ITS AUTHORIZED OFFICE THIS 5TH DAY OF MARCH, 2021

(Seal)

John Glomb, President & CEO
Philadelphia Indemnity Insurance Company

On this 5th day of March, 2021 before me came the individual who executed the preceding instrument, to me personally known, and being by me duly sworn said that he is the therein described and authorized officer of the **PHILADELPHIA INDEMNITY INSURANCE COMPANY**, that the seal affixed to said instrument is the Corporate seal of said Company; that the said Corporate Seal and his signature were duly affixed

Commonwealth of Pennsylvania - Notary Seal
Vanessa Mckenzie, Notary Public
Montgomery County
My commission expires November 3, 2024
Commission number 1368394
Member, Pennsylvania Association of Notaries

Notary Public Vanessa McKenzie

residing at Bala Cynwyd, PA

My commission expires November 3, 2024

I, Edward Sayago, Corporate Secretary of PHILADELPHIA INDEMNITY INSURANCE COMPANY, do hereby certify that the foregoing resolution of the Board of Directors and the Power of Attorney issued pursuant thereto on the 5th day March, 2021 are true and correct and are still in full force and effect I do further certify that John Glomb, who executed the Power of Attorney as President, was on the date of execution of the attached Power of Attorney the duly elected President of PHILADELPHIA INDEMNITY INSURANCE COMPANY

In Testimony Whereof I have subscribed my name and affixed the facsimile seal of each Company this 5 day of July 2023

Edward Sayago, Corporate Secretary
**PHILADELPHIA INDEMNITY INSURANCE COMPANY**

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/18/2023)

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Fountain Medical Supplies Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): 13111948-1710 EIN #88-2244359

Physical Address: 1223 S 1840 W

City: Orem State: Utah Zip: 84058

Mailing Address (if different from physical address): same as above

City: State: Zip:

Telephone: 801-980-9023 Website: www.fountainmedicalsupplies.com

Licensing Company Email: info@fountainmedicalsupplies.com

First: David Middle: Matthew Last: Harrington

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] W. Fox Hollow Drive

City: Saratoga Springs State: Utah Zip: 84045

Telephone: [redacted] Email: david@fountainmedicalsupplies.com

Are you a citizen of the United States? ■ Yes ☐ No

| | | |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| | | |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | ✔ | |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | ✔ | |

| School Name | From - To (MM/YY – MM/YY) | | |
|---|---|---|---|
| Brigham Young University | 4/2013-8/2018 | | |
| Address | City | State | Zip |
| 1060 E Campus | Provo | Utah | 84604 |
| Diploma/Degree obtained, if any | | | |
| Bachelor of Exercise Science | | | |

| School Name | From - To (MM/YY – MM/YY) | | |
|---|---|---|---|
| SLCC | 5/2012-4/2013 | | |
| Address | City | State | Zip |
| 4600 S Redwood Road | Salt Lake City | Utahh | 84123 |
| Diploma/Degree obtained, if any | | | |

| School Name | From - To (MM/YY – MM/YY) | | |
|---|---|---|---|
| BYU Idaho | 1/2012-4/2012 | | |
| Address | City | State | Zip |
| 525 S Center St | Rexburg | Idaho | 83460 |
| Diploma/Degree obtained, if any | | | |

| School Name | From - To (MM/YY – MM/YY) | | |
|---|---|---|---|
| MSJC | 1/2012-5/2012 | | |
| Address | City | State | Zip |
| 28237 La Piedra Rd | Menifee | CA | 92584 |
| Diploma/Degree obtained, if any | | | |

| School Name | From - To (MM/YY – MM/YY | | |
|---|---|---|---|
| Great Bridge High School | 1994-1997 | | |
| Address | City | State | Zip |
| 301 Hanbury Rd | Chesapeake | VA | 23322 |
| Diploma/Degree obtained, if any | | | |
| High School graduate | | | |

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 03/2019-current | [redacted] W Fox Hollow Drive | Saratoga Springs | Utah | 84045 |
| 1/2013-3/2019 | [redacted] W. Wood Springs Drive | West Jordan | Utah | 84081 |
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**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| | | | |
|---|---|---|---|
| Business Name: Fountain Medical Supplies Inc. | | | From - To (MM/YY – MM/YY): 5/2021-current |
| Business Address: 1223 S 1840 W | City: Orem | State: Utah | Zip: 84058 |
| Phone: 801-908-9023 | Title: CEO/owner | | |
| Description of Duties: Operations manager, inventory management, designated representative, purchasing and receiving pharmaceuticals and medical supplies. | | | |

| | | | |
|---|---|---|---|
| Business Name: Fountain IV Therapy | | | From - To (MM/YY – MM/YY): 07/2021-10/2022 |
| Business Address: 180 N. University Ave. STE #270 | City: Provo | State: Utah | Zip: 84601 |
| Phone: 385-388-1941 | Title: CEO-director of operations | | |
| Description of Duties: Inventory management, purchasing and receiving, pharmaceutical managment, operations manager. | | | |

| | | | |
|---|---|---|---|
| Business Name | | | From - To (MM/YY – MM/YY) |
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| | | | |
|---|---|---|---|
| Business Name | | | From - To (MM/YY – MM/YY) |
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| | | | |
|---|---|---|---|
| Business Name | | | From - To (MM/YY – MM/YY) |
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✔ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

N/A

Original Signature (electronic, copies or stamps not accepted)

7/6/2023

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

David Harrington

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/6/2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Utah, ss. County of Utah

I, David Harrington, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

7/10/23

**Date**

Subscribed and Sworn to before me this 10th day of July, 2023.

**Notary Public Signature**

JOEL CONDIT
NOTARY PUBLIC • STATE OF UTAH
COMMISSION NO. 724667
COMM. EXP. 05/12/2026

(Seal)

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

**Section 1: Pharmacy/Wholesaler Information**

Name of Pharmacy/Wholesaler Fountain Medical Supplies Inc.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 1223 S. 1840 W.

City Orem State Utah Zip 84058

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 385-338-1941 Website www.fountainmedicalsupplies.com

Licensing Company Email info@fountainmedicalsupplies.com

**Section 2: Personal Information**

First David Middle Matthew Last Harrington

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted] S. 1840 W.

City Orem State Utah Zip 84058

Telephone [redacted] Email david@fountainmedicalsupplies.com

Are you a citizen of the United States? ■ Yes ☐ No

| Section 3: Military Service (NRS 622.400) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Child Support Requirements (NRS 425.520, 425.540, 630.330) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | ✔ | |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | ✔ | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Brigham Young University | | 4/13-8/18 | |
| Address | City | State | Zip |
| Brigham Young University | Provo | Utah | 84602 |
| Diploma/Degree obtained, if any | | | |
| Bachelor degree in Exercise Science | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Salt Lake Community College | | 5/12-4/13 | |
| Address | City | State | Zip |
| 4600 S Redwood Rd | Salt Lake City | Utah | 84123 |
| Diploma/Degree obtained, if any | | | |
| none | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| BYU Idaho | | 1/12-4/12 | |
| Address | City | State | Zip |
| 525 S Center St | Rexburg | ID | 83460 |
| Diploma/Degree obtained, if any | | | |
| none | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Mount San Jacinto College | | 1/12-5/12 | |
| Address | City | State | Zip |
| 1499 N State St | San Jacinto | CA | 92583 |
| Diploma/Degree obtained, if any | | | |
| none | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| Riverside Community College | | 2/01-6/04 | |
| Address | City | State | Zip |
| 4800 MAgnolia Ave | Riverside | CA | 92506 |
| Diploma/Degree obtained, if any | | | |
| none | | | |

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 3/19-current | [redacted]W. Fox Hollow Drive | Saratoga Springs | Utah | 84045 |
| 7/18-3/19 | [redacted] W 13490 S | Draper | Utah | 84020 |
| 2/12-7/18 | 5[redacted]W. Wood Spring Dr. | West Jordan | Utah | 84081 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

[redacted]

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Fountain Medical Supplies Inc. | | | 5/22-current | |
| Business Address | | City | State | Zip |
| 1223 S. 1840 W. | | Orem | Utah | 84058 |
| Phone | Title | | Number of Employed Hours | |
| 385-338-1941 | CEO/owner | | 6,500+ | |
| Description of Duties | | | | |
| Purchasing, inventory, distribution, documentation, warehouse management, quality and compliance | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Fountain IV Therapy | | | 8/21-5/22 | |
| Business Address | | City | State | Zip |
| 180 N. University Ave STE 270 | | Provo | Utah | 84601 |
| Phone | Title | | Number of Employed Hours | |
| 385-338-1941 | CEO/owner | | 7,200+ | |
| Description of Duties | | | | |
| Purchasing, inventory, management, quality and compliance | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| | | | | |
| Phone | Title | | Number of Employed Hours | |
| | | | | |
| Description of Duties | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| | | | | |
| Phone | Title | | Number of Employed Hours | |
| | | | | |
| Description of Duties | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| | | | | |
| Phone | Title | | Number of Employed Hours | |
| | | | | |
| Description of Duties | | | | |
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Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 3 Applicant Disclosure / Signature Acknowledgement | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

N/A

Original Signature (electronic, copies or stamps not accepted)

12/16/2022

Date

I, David Matthew Harrington, **certify that as the designated representative for**

Fountain Medical Supplies Inc.,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. X I am at least 21 years of age;
3. X I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. X I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. X I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. X I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. X I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

David Harrington

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/16/2022

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

David Matthew Harrington

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/16/2022

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of UT, ss. County of UT

I, DAVID HARRINGTON, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

12/16/2022

**Date**

Subscribed and Sworn to before me this 16 day of December

**Notary Public Signature**

HILARY NICE
Notary Public - State of Utah
Comm. No. 713394
My Commission Expires on
Aug 4, 2024

**(Seal)**

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Name of MDEG Fountain Medical Supplies Inc. MDEG License # (if applicable) 13111948-171(

Physical Address 1223 S. 1840 W.

City Orem State Utah Zip 84058

Mailing Address (if different from physical address) same

City _____ State _____ Zip _____

Telephone 951-283-6643 Website www.fountainmedicalsupplies.com

Licensing Company Email info@fountainmedicalsupplies.com

First David Middle Matthew Last Harrington

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Addres[redacted] W. Fox Hollow Drive

City Saratoga Springs State Utah Zip 84045

Telephone [redacted] Email david@fountainmedicalsupplies.com

Are you a citizen of the United States? ■ Yes ☐ No

| | | |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| | | |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | ✔ | |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | ✔ | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Brigham Young University | | 4/2013-8/2018 | |
| **Address** | **City** | **State** | **Zip** |
| 1060 E Campus Dr. | Provo | Utah | 84604 |
| **Diploma/Degree obtained, if any** | | | |
| Bachelor of Exercise Science | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| SLCC | | 5/2012-4/2013 | |
| **Address** | **City** | **State** | **Zip** |
| 4600 S Redwood Road | SLC | Utah | 84123 |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| MSJC | | 1/2012-5/2012 | |
| **Address** | **City** | **State** | **Zip** |
| 28237 La Piedra Rd | Menifee | CA | 92584 |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Great Bridge High School | | 1994-1997 | |
| **Address** | **City** | **State** | **Zip** |
| 301 Hanbury Rd | Chesapeake | VA | 23322 |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 3/2019-current | [redacted]W. Fox Hollow Drive | Saratoga Springs | UT | 84045 |
| 1/2013-3/2019 | [redacted]W. Wood Spring Dr | West Jordan | UT | 84081 |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

| Business Name | | From - To (MM/YY – MM/YY) |
|---|---|---|
| Fountain Medical Supplies Inc | | 5/2021-current |
| **Business Address** | **City** | **State / Zip** |
| 1223 S. 1840 W. | Oerm | Utah 84058 |
| **Phone** | **Title** | **Number of Employed Hours** |
| 801-980-9023 | Designated Representative, CEO | 50 hrs/wk |
| **Description of Duties** | | |
| Inventory management, designated rep, operations manager, purchasing and receiving pharmaceuticals | | |

| Business Name | | From - To (MM/YY – MM/YY) |
|---|---|---|
| Fountain IV Therapy | | 7/2021-10-2022 |
| **Business Address** | **City** | **State / Zip** |
| 180 N. University Ave. STE #270 | Provo | Utah 84601 |
| **Phone** | **Title** | **Number of Employed Hours** |
| 385-338-1941 | CEO-director of operations | 50 hrs/wk |
| **Description of Duties** | | |
| Inventory management, purchasing and receiving, pharmaceutical management, operations manager | | |

| Business Name | | From - To (MM/YY – MM/YY) |
|---|---|---|
| | | |
| **Business Address** | **City** | **State / Zip** |
| | | |
| **Phone** | **Title** | **Number of Employed Hours** |
| | | |
| **Description of Duties** | | |
| | | |

| Business Name | | From - To (MM/YY – MM/YY) |
|---|---|---|
| | | |
| **Business Address** | **City** | **State / Zip** |
| | | |
| **Phone** | **Title** | **Number of Employed Hours** |
| | | |
| **Description of Duties** | | |
| | | |

| Business Name | | From - To (MM/YY – MM/YY) |
|---|---|---|
| | | |
| **Business Address** | **City** | **State / Zip** |
| | | |
| **Phone** | **Title** | **Number of Employed Hours** |
| | | |
| **Description of Duties** | | |
| | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| | | |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | X |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state? | | X |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline. | | X |

**Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>**

**This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

8/8/23
Date

I, David Harrington, **certify that as the MDEG Administrator for**

Fountain Medical Supplies,

**that I (initial that you have read and meet the following requirements):**

1. ___ Have a high school diploma or its equivalent;
2. ___ Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. ___ Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. ___ Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

David Harrington

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/8/23

Date

| Board Use Only | Date Received: _____ |
|---|---|

**Full list of employees for Fountain Medical Supplies Inc.**

David Harrington- CEO/President/Chairman
100% ownership of Fountain Medical Supplies Inc.
[redacted]W Fox Hollow Dr.
Saratoga Springs, UT 84045

Andrea Harrrington RN- Director of Compliance/Treasurer/Secretary
[redacted]W Fox Hollow Dr.
Saratoga Springs, UT 84045

# 4GG

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

**Non-Refundable $1,000 Fee**

Rev (08/17/2022)

| Where is the facility located? | ☐ Nevada ■ Out-of-State |
|---|---|

| Type of Application (check applicable box) | | Wholesaler Business Type (check applicable box) |
|---|---|---|
| ■ New Wholesaler<br>☐ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH _____ | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: MD Logistics LLC

Physical Address: 2000 Garner Business Park Drive

City: Garner State: NC Zip: 27529

Mailing Address (if different from physical address): 1301 Perry Road

City: Plainfield State: IN Zip: 46168

Telephone: (919) 926-0854 Website: www.mdlogistics.com

Name of Designated Representative (DR): Jonathan A. Aviles

Licensing Company Email: info@mdlogistics.com DR Email: javiles@mdlogistics.com

| Entities the Wholesaler will Serve (✓ all applicable) | Products to be Handled or Wholesaled (✓ all applicable) | Type of Wholesaling (✓ all applicable) |
|---|---|---|
| ■ Pharmacies | ☐ Dangerous Drugs | ☐ Manufacturer |
| ■ Practitioners | ☐ Controlled Substances | ☐ Repacker |
| ■ Hospitals | ☐ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ■ Wholesalers | ■ Others: Presription Drugs | ■ Warehouse |
| ☐ Veterinarians | | ☐ Retail pharmacy wholesale distributor |
| ■ Others: 3PL's | | ■ Others: 3pl |

| Section 2: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✔ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | ✔ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | ✔ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✔ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | NA |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

NA

Original Signature (electronic, copies or stamps not accepted)

5-17-23

Date

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: Merck
Address: 770 Sumneytown Pike City: West Point State: PA Zip: 19486

Name: Novo Nordisk
Address: 800 Scudders Mill Road, Suite 1A108 City: Plainsboro State: NJ Zip: 08536

Name: Viatris
Address: 2898 Manufacturers Rd., Office Phase 2 City: Greensboro State: NC Zip: 27406

Name:
Address: City: State: Zip:

**Section 4: Publicly Traded Corporation**

State of Incorporation:
Parent Company (if any): NA
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: NY
Parent Company (if any): Nippon Express USA, Inc.
Corporation/Organization Name: Nippon Express USA, Inc.
Mailing Address: 800 North IL Route 83
City: Wood Dale State: IL Zip: 60191
Telephone: 708-304-9904 Email: Brad.Hanna@nipponexpress.com
Contact Person Name: Bradley Hanna, VP and Gen. Counsel

**Section 6: Partnership**

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name: NA

**Section 7: Sole Owner**

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Ⓐ -X Attached copy MDL DDA cert

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: N/A | ✔ | |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | | ✔ |
| 1. Copy of FDA registration<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of <u>all</u> Officers and Directors.** | ✓ | ✓ Ⓑ | | |
| • **List the <u>top four</u> corporation shareholders and their percent ownership.** | ✓ | | | |
| • **List of <u>all</u> corporation shareholders and their percent ownership.** | | ✓ Ⓑ | | |
| • **List of <u>all</u> partners and their percent ownership.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. | ✓ | ✓ Ⓒ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ Ⓓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ Ⓔ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** | ✓ | ✓ Ⓕ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). | ✓ | ✓ | ✓ | ✓ |
| **<u>ONLY</u> Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

MD Logistics LLC

Facility Name

John C. Wade

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

5-17-2023

Date

| Board Use Only | Date Received: 5-30-23 | Amount: 1000.00 CC |
|---|---|---|

MD Logistics, LLC Owner/Officer Information

| Name | Title | Designated Rep | NABP E Profile ID | Home | Business | Home / Cell | Business | E-Mail | % Owned |
|---|---|---|---|---|---|---|---|---|---|
| John Andrew Sell | President and CEO | X | X | [redacted]East 116th Street, Carmel, IN 46033 | 1301 Perry Road, Plainfield, IN 46168 | ([redacted] | (317) 838-8900 | jsell@mdlogistics.com | 0 |
| Chad Palmer Hodges | Vice President | X | X | [redacted]Whiting Bay Drive, Brownsburg, IN, 46112 | 1301 Perry Road, Plainfield, IN 46168 | [redacted] | (317) 838-8900 | chodges@mdlogistics.com | 0 |
| Robert Francis Sternberg | Assoc.Director Shared Pharma | X | | [redacted]Farmhouse Drive, Apex, NC, 27502 | 2000 Garner Business Park Drive Suite 100 Garner, NC 27529 | [redacted] | (919) 926-0854 | bsternberg@mdlogistics.com | 0 |
| Jonathan Alexander Aviles | Manager Operations | **2000** | | [redacted]Tumbling Stone Way, Garner, NC, 27529 | 2000 Garner Business Park Drive Suite 100 Garner, NC 27529 | [redacted] | (919) 926-0854 | javiles@mdlogistics.com | 0 |

# NORTH CAROLINA
## Department of the Secretary of State

(E)

## CERTIFICATE OF AUTHORIZATION

I, ELAINE F. MARSHALL, Secretary of State of the State of North Carolina, do hereby certify that

**MD LOGISTICS, INC.**

a corporation organized under the laws of Indiana was authorized to transact business in the State of North Carolina by issuance of a certificate of authority on the 7th day of November, 2012.

I FURTHER certify that the said corporation's certificate of authority is not suspended for failure to comply with the Revenue Act of the State of North Carolina; that the said corporation's certificate of authority is not revoked for failure to comply with the provisions of the North Carolina Business Corporation Act; that its most recent annual report required by G.S. 55-16-22 has been delivered to the Secretary of State; and that a certificate of withdrawal has not been issued in the name of the said corporation as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Raleigh, this 24th day of May, 2023.

Elaine F. Marshall

**Secretary of State**

Scan to verify online.

Certification# 116982557-1 Reference# 20182066- Page: 1 of 1
Verify this certificate online at https://www.sosnc.gov/verification

# License Search

License Group/Division (Optional)

Food & Drug – Prescription Drug Distribution – Registration &

License Type

All

## Advanced Search

Licensee

md logistics

License Number

1684

Address

Address

Counties

All

Status

State

*** NONE ***

Search ☐ Check for exact text search

Previous 1 Next Excel

**MD LOGISTICS LLC**
**2000 GARNER BUSINESS PARK DRIVE**
**GARNER, NC 27529**

- **License Number:** 1684
- **County:**
- **Owner:** Food & Drug – Prescription Drug Distribution – Registration & Licensing
- **License Type:** Third Party Logistic Provider
- **Expiration Date:** 12/31/2023
- **Status:** ActiveInGoodStanding
- **Issue Date:** 12/13/2022

(C)

## John Wade

**From:** Redd, Shannon <Shannon.Redd@ncagr.gov>
**Sent:** Thursday, March 16, 2023 8:13 AM
**To:** John Wade
**Subject:** RE: [External] verification??

**EXTERNAL MAIL:** This email originated from outside the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good Morning,

You are correct, we do not complete license verifications.

You may visit our website for online verification - NCDA&CS - Food & Drug Protection - Drug Program (ncagr.gov)

Thanks,

Shannon B. Redd
Administrative Specialist I
NCDA&CS
Food & Drug Protection Division
1070 Mail Service Center
Raleigh, NC 27699-1070
984.236.4820
Shannon.Redd@ncagr.gov

NCDA&CS AGRICULTURAL SCIENCES CENTER

**From:** John Wade <jwade@MDLogistics.com>
**Sent:** Wednesday, March 15, 2023 2:43 PM
**To:** Redd, Shannon <Shannon.Redd@ncagr.gov>
**Subject:** [External] verification??

**CAUTION:** External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to Report Spam.

Shannon,

Delaware licensing requirement is for this form to be completed by the state in which the facility is located, and to be mailed to their address on the form.

I do recall that NC may not perform such license verification? If not, I wanted to be sure to send this to you. But I don't recall.

Our MDL site data is:

(C)

| | | | | | |
|---|---|---|---|---|---|
| NC | North Carolina 2000 | 2000 | 1684 | 3PL | Third Party Logis |

Address is: 2000 Garner Business Park Drive, Garner, 27529.

John Wade

**From:** John Wade <jcwade@icloud.com>
**Sent:** Wednesday, March 15, 2023 2:35 PM
**To:** John Wade <jwade@MDLogistics.com>
**Subject:**

EXTERNAL MAIL: This email originated from outside the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Sent from my iPhone

# NC Dept. of Agriculture & Consumer Services

## Food & Drug Protection Division

**Firm Name:** MD LOGISTICS LLC

**Address:** 2000 GARNER BUSINESS PARK DRIVE GARNER, NC 27529

**License Type:** Third Party Logistic Provider

**License Number:** 1684

**Status:** Active - in good standing

**Discipline:** No

**Issue Date:** 12/8/2022

**Original Issue:** 12/8/2022

**Expiration Date:** 12/31/2023

(B)

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

## PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 60138507

Application/License No. _____

MD Logistics, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1301 Perry Road, Plainfield, IN 46168 (Address of Applicant/Principal), as PRINCIPAL, and Capitol Indemnity Corporation (Surety Company), a corporation organized under the laws of the state of Wisconsin (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1600 Aspens Commons, Suite 300, Middleton, WI 53562 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on August 31, 2020 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

* Additional locations to be added to this bond.

2150 Stanley Road, Plainfield, IN 46168
12125 Moya Blvd., Reno, NV 89506

# CAPITOL INDEMNITY CORPORATION
# POWER OF ATTORNEY

60138507

**KNOW ALL MEN BY THESE PRESENTS,** That the **CAPITOL INDEMNITY CORPORATION,** a corporation of the State of Wisconsin, having its principal offices in the City of Middleton, Wisconsin, does make, constitute and appoint

---------- SARABETH SCOTT; ANTHONY BALZANO; DEBORAH M. ROTH; ROSALIE S. SMITH; JOANN SMITH ----------

its true and lawful Attorney(s)-in-fact, to make, execute, seal and deliver for and on its behalf as surety, and as its act and deed, any and all bonds, undertakings and contracts of suretyship, provided that no bond or undertaking or contract of suretyship executed under this authority shall exceed in amount the sum of

----------ALL WRITTEN INSTRUMENTS IN AN AMOUNT NOT TO EXCEED: $20,000,000.00 ----------

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of **CAPITOL INDEMNITY CORPORATION** at a meeting duly called and held on the 8th day of January, 2002.

"**RESOLVED**, that the President, Executive Vice President, Vice President, Secretary or Treasurer, acting individually or otherwise, be and they hereby are granted the power and authorization to appoint by a Power of Attorney for the purposes only of executing and attesting bonds and undertakings, and other writings obligatory in the nature thereof, one or more resident vice-presidents, assistant secretaries and attorney(s)-in-fact, each appointed to have the powers and duties usual to such offices to the business of this company; the signature of such officers and seal of the Company may be affixed to any such power of attorney or to any certificate relating thereto by facsimile, and any such power of attorney or certificate bearing such facsimile signatures or facsimile seal shall be valid and binding upon the Company, and any such power so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking or other writing obligatory in the nature thereof to which it is attached. Any such appointment may be revoked, for cause, or without cause, by any of said officers, at any time."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and authority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner – Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

**IN WITNESS WHEREOF,** the **CAPITOL INDEMNITY CORPORATION** has caused these presents to be signed by its officer undersigned and its corporate seal to be hereto affixed duly attested, this 3rd day of May, 2017

Attest:

John E. Rzepinski
Vice President, Treasurer & CFO

Suzanne M. Broadbent
Assistant Secretary

**CAPITOL INDEMNITY CORPORATION**

Stephen J. Sills
CEO & President

STATE OF WISCONSIN }
COUNTY OF DANE } S.S.:

On the 3rd day of May, 2017 before me personally came Stephen J. Sills, to me known, who being by me duly sworn, did depose and say: that he resides in the County of New York, State of New York; that he is President of **CAPITOL INDEMNITY CORPORATION,** the corporation described in and which executed the above instrument; that he knows the seal of the said corporation; that the seal affixed to said instrument is such corporate seal; that it was so affixed by order of the Board of Directors of said corporation and that he signed his name thereto by like order.

David J. Regele
Notary Public, Dane Co., WI
My Commission Is Permanent

STATE OF WISCONSIN }
COUNTY OF DANE } S.S.:

I, the undersigned, duly elected to the office stated below, now the incumbent in **CAPITOL INDEMNITY CORPORATION,** a Wisconsin Corporation, authorized to make this certificate, **DO HEREBY CERTIFY** that the foregoing attached Power of Attorney remains in full force and has not been revoked; and furthermore, that the Resolution of the Board of Directors, set forth in the Power of Attorney is now in force.

Signed and sealed at the City of Middleton, State of Wisconsin this 31st day of August 20 20.

Antonio Celii
General Counsel, Vice President & Secretary

THIS DOCUMENT IS NOT VALID UNLESS PRINTED ON GRAY SHADED BACKGROUND WITH A RED SERIAL NUMBER IN THE UPPER RIGHT HAND CORNER. IF YOU HAVE ANY QUESTIONS CONCERNING THE AUTHENTICITY OF THIS DOCUMENT CALL 800-475-4450

# BOND RIDER

To be attached to and form a part of **Pharmaceutical Wholesaler Surety Bond # 60138507** Dated **August 31, 2020**, with **MD Logistics LLC**, as Principal, and **Capitol Indemnity Corporation** as Surety, in favor of **Nevada State Board of Pharmacy**, as Obligee.

It is understood and agreed that the Bond is changed or revised in the particulars as indicated below.

**2000 Garner Business Park Dr., Garner, NC 27259 to be added as additional location under this bond.**

Said Bond shall be subject to all its terms, conditions, and limitations, except as herein expressly modified.

This Bond Rider shall become effective: **April 17, 2023**

Signed, Sealed and Dated April 17, 2023

CAPITOL INDEMNITY CORPORATION
SURETY

By: Deborah M. Roth
Deborah M. Roth, Attorney-in-Fact

American Contracting Services, Inc.
781 Neeb Road
Cincinnati, OH 46140
(317) 563-3228

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 31st day of August, 2020.

APPLICANT/PRINCIPAL

COMPANY

MD Logistics, LLC

Authorized Representative

SURETY

Capitol Indemnity Company

Surety Company's Representative

Deborah M. Roth, Attorney-in-fact

print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A

Nevada Resident Agent

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.

(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.

(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.

(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.

(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.

(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.

(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 31st day of August, 2020.

APPLICANT/PRINCIPAL

COMPANY

MD Logistics, LLC

Authorized Representative

SURETY

Capitol Indemnity Company

Surety Company's Representative

Deborah M. Roth, Attorney-in-fact

print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A

Nevada Resident Agent

Posted February 20, 2020

Lock Fields

# CAPITOL INDEMNITY CORPORATION
# POWER OF ATTORNEY

60138507
Bond Number

**KNOW ALL MEN BY THESE PRESENTS.** That the **CAPITOL INDEMNITY CORPORATION**, a corporation of the State of Wisconsin; having its principal offices in the City of Middleton, Wisconsin, does make, constitute and appoint

----------ANTHONY BALZANO; DEBORAH M ROTH; ROSALIE S SMITH; JOANN SMITH; SHARON RAINEY ----------

its true and lawful Attorney(s)-in-fact, to make, execute, seal and deliver for and on its behalf, as surety, and as its act and deed, any and all bonds, undertakings and contracts of suretyship, provided that no bond or undertaking or contract of suretyship executed under this authority shall exceed in amount the sum of

----------ALL WRITTEN INSTRUMENTS IN AN AMOUNT NOT TO EXCEED $20,000,000.00 ----------

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of **CAPITOL INDEMNITY CORPORATION** at a meeting duly called and held on the 15th day of May, 2002.

"**RESOLVED**, that the President, Executive Vice President, Vice President, Secretary or Treasurer, acting individually or otherwise, be and they hereby are granted the power and authorization to appoint by a Power of Attorney for the purposes only of executing and attesting bonds and undertakings, and other writings obligatory in the nature thereof, one or more resident vice-presidents, assistant secretaries and attorney(s)-in-fact, each appointee to have the powers and duties usual to such offices to the business of this company; the signature of such officers and seal of the Company may be affixed to any such power of attorney or to any certificate relating thereto by facsimile, and any such power of attorney or certificate bearing such facsimile signatures or facsimile seal shall be valid and binding upon the Company, and any such power so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking or other writing obligatory in the nature thereof to which it is attached. Any such appointment may be revoked, for cause, or without cause, by any of said officers, at any time."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and authority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner – Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

**IN WITNESS WHEREOF**, the **CAPITOL INDEMNITY CORPORATION** has caused these presents to be signed by its officer undersigned and its corporate seal to be hereto affixed duly attested, this 1st day of January, 2020.

**Attest:**

Ryan J Byrnes
Senior Vice President,
Chief Financial Officer and Treasurer

Suzanne M Broadbent
Suzanne M. Broadbent
Assistant Secretary

CAPITOL INDEMNITY CORPORATION

John L. Sennott, Jr.
Chief Executive Officer and President

STATE OF WISCONSIN
COUNTY OF DANE } S.S.

On the 1st day of January, 2020 before me personally came John L. Sennott, Jr., to me known, who being by me duly sworn, did depose and say: that he resides in the County of Hartford, State of Connecticut; that he is Chief Executive Officer and President of **CAPITOL INDEMNITY CORPORATION**, the corporation described in and which executed the above instrument; that he knows the seal of the said corporation, that the seal affixed to said instrument is such corporate seal, that it was so affixed by order of the Board of Directors of said corporation and that he signed his name thereto by like order.

David J. Regele
Notary Public, Dane Co., WI
My Commission Is Permanent

STATE OF WISCONSIN
COUNTY OF DANE } S.S.

I, the undersigned, duly elected to the office stated below, now the incumbent in **CAPITOL INDEMNITY CORPORATION**, a Wisconsin Corporation, authorized to make this certificate, **DO HEREBY CERTIFY** that the foregoing attached Power of Attorney remains in full force and has not been revoked; and furthermore, that the Resolution of the Board of Directors, set forth in the Power of Attorney is now in force.

Signed and sealed at the City of Middleton, State of Wisconsin this 17th day of April 20 23

Andrew B. Diaz-Matos
Senior Vice President, General Counsel and Secretary

THIS DOCUMENT HAS BEEN GENERATED FOR A SPECIFIC BOND. IF YOU HAVE ANY QUESTIONS CONCERNING THE AUTHENTICITY OF THIS DOCUMENT CALL 800-475-4450.

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

### Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler MD Logistics LLC

Pharmacy/Wholesaler License # (if applicable) N/A

Physical Address 2000 Garner Business Park Drive

City Garner State NC Zip 27529

Mailing Address (if different from physical address) 1301 Perry Road

City Plainfield State IN Zip 46168

Telephone 919-826-0854 Website www.mdlogistics.com

Licensing Company Email jwade@mdlogistics.com

### Section 2: Personal Information

First Jonathan Middle Alexander Last Aviles

Alias(es, nicknames, name changes, etc.) NA

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] Tumbling Stone Way

City Garner State NC Zip 27529

Telephone [redacted] Email javiles@mdlogistics.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | NA |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Pike High School | | 08/11- 05/15 | |
| **Address** | **City** | **State** | **Zip** |
| 5401 West 71st Street | Indianapolis | IN | 46268 |
| Diploma/Degree obtained, if any | | | |
| Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 10/22 - Current | [redacted]Tumbling Stone Way | Garner | NC | 27529 |
| 05/22 - 10/22 | [redacted] Excalibur Court | Indianapolis | IN | 46268 |
| 05/20 - 05/22 | [redacted]Pendragon Blvd. | Indianapolis | IN | 46268 |
| 05/18 - 05/20 | [redacted]Bradbury Drive | Plainfield | IN | 46168 |
| 05/16 - 05/18 | [redacted]Kurtis Blvd., Unit A | Indianapolis | IN | 46224 |
| 11/96 - 05/16 | [redacted]Fullwood Court | Indianapolis | IN | 46224 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| MD Logistics LLC | | | 10/22 - Current | |
| **Business Address** | | **City** | **State** | **Zip** |
| 2000 Garner Business Park Drive | | Garner | NC | 27529 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 919-926-0854 | Operations manager and designated rep. | | 40 / Week 6000+ | |
| **Description of Duties** | | | | |
| responsible for the overall management of receiving, storage, inventory, warehousing, and distribution of MDL drug products. Also perform all duties of designated representative. | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| MD Logistics LLC | | | 05/18 - 10/22 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 1301 Perry Road | | Plainfield | IN | 46168 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 317-838-8900 | Operations | | 40+ / week 6000+ | |
| **Description of Duties** | | | | |
| responsible for the overall supervision of the warehousing and shipping operations. Supervise receiving, storage, inventory, warehousing, and distribution of MDL drug products | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

Continue on next page if additional space is needed.

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

N/A

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | NA |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| NA | | | | |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| Reason/Charge | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| Name of Business/Industry/Entity | | | | |

**Provide explanation below:**

NA

N/A

_____

Original Signature (electronic, copies or stamps not accepted)

N/A

_____

Date

I, Jonathan A. Aviles, **certify that as the designated representative for**

MD Logistics LLC, Garner, NC,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. JA I am at least 21 years of age;
3. JA I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JA I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JA I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JA I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JA I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jonathan Aviles
Print Name (First, Last)

Jonathan Aviles
Original Signature (electronic, copies or stamps not accepted)

17 May 2023
Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Jonathan . Aviles

Print Name (First, Last)

Jonathan Aviles — 17 May 2023

Original Signature (electronic, copies or stamps not accepted) — Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Indiana, ss. County of ~~Marion~~ JW 5-17-23 Marion

I, Jonathan Aviles, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Jonathan Aviles — 17 May 2023

**Original Signature** — **Date**

Subscribed and Sworn to before me this 17 day of May.

**Notary Public Signature**

JOHN C. WADE
Notary Public - Seal
Marion County - State of Indiana
Commission Number NP0747623
My Commission Expires March 16, 2031

**(Seal)**

MDL - Garner, NC site Employees 5/17/23 (A)

| Employee ID | Site | Last Name | First Name | Station | Hire Date |
|---|---|---|---|---|---|
| NAlston | 8 | Alston | Nora | ASSOCIATE;FORKLIFT OPERATOR | 5/4/2023 |
| NAnsong-Danyki | 8 | Ansong-Danyki | Nana | ASSOCIATE | 3/14/2023 |
| JAVILES | 8 | AVILES | JONATHAN | ADMINISTRATOR;DESIGNATED REP;FORKLIFT OPERATOR;MANAGER | 3/7/2018 |
| VBarajas | 8 | Barajas | Victor | ASSOCIATE;FORKLIFT OPERATOR | 10/27/2022 |
| IBlanco | 8 | Blanco | Israel | ASSOCIATE;FORKLIFT OPERATOR | 2/16/2023 |
| JBlandenburg | 8 | Blandenburg | Jessica | ASSOCIATE;FORKLIFT OPERATOR | 5/9/2023 |
| JEagal | 8 | Eagal | Jeffrey | ASSOCIATE;FORKLIFT OPERATOR | 5/9/2023 |
| GFerguson | 8 | Ferguson | Guyvon | LEAD | 5/16/2023 |
| BGreer | 8 | Greer | Billie | ADMINISTRATOR | 11/14/2022 |
| DEHall | 8 | Hall | Deidre | ASSOCIATE;FORKLIFT OPERATOR | 3/16/2023 |
| SHargrove | 8 | Hargrove | Shelton | ASSOCIATE;FORKLIFT OPERATOR | 4/25/2023 |
| MIHarris | 8 | Harris | Michael | ASSOCIATE;FORKLIFT OPERATOR | 3/14/2023 |
| PHolt | 8 | Holt | Patricia | LEAD | 3/9/2023 |
| AHughes | 8 | Hughes | Al | ASSOCIATE;FORKLIFT OPERATOR | 4/20/2023 |
| PKafle | 8 | Kafle | Pramod | LEAD | 5/16/2023 |
| Imarcano | 8 | Marcano | Isaias | ASSOCIATE;FORKLIFT OPERATOR | 2/14/2023 |
| MMarlin | 8 | Marlin | Mikeo | ASSOCIATE;FORKLIFT OPERATOR | 3/30/2023 |
| BNewell | 8 | Newell | Brian | FORKLIFT OPERATOR;SUPERVISOR | 1/17/2023 |
| TNgoma | 8 | Ngoma | Titi | ASSOCIATE;FORKLIFT OPERATOR | 5/9/2023 |
| Lortega | 8 | Ortega | Luis | ASSOCIATE;FORKLIFT OPERATOR | 1/30/2023 |
| COtter | 8 | Otter | Christopher | LEAD | 9/9/2019 |
| JURobinson | 8 | Robinson | Juanita | LEAD | 4/27/2023 |
| JORodriguez | 8 | Rodriguez | Joan | ASSOCIATE;FORKLIFT OPERATOR | 2/21/2023 |
| IRosario | 8 | Rosario | Ivan | ASSOCIATE | 4/4/2023 |
| SRose | 8 | Rose | Samuel | FORKLIFT OPERATOR;SUPERVISOR | 10/18/2022 |
| SSciplone | 8 | Sciplone | Scott | ASSOCIATE;FORKLIFT OPERATOR | 10/18/2022 |
| JSmith93 | 8 | Smith93 | Jordan | LEAD | 5/4/2023 |
| HSnipes | 8 | Snipes | Heather | ASSOCIATE;FORKLIFT OPERATOR | 5/9/2023 |
| BSternberg | 8 | Sternberg | Bob | ASSOCIATE DIRECTOR | 5/30/2022 |
| SVargas | 8 | Vargas | Stephen | ASSOCIATE;FORKLIFT OPERATOR | 5/2/2023 |
| CVinson | 8 | Vinson | Carrington | LEAD | 3/16/2023 |
| AnWalker | 8 | Walker | Aniqwa | ASSOCIATE;FORKLIFT OPERATOR | 5/9/2023 |
| JWalters | 8 | Walters | Jadavion | ASSOCIATE;FORKLIFT OPERATOR | 3/27/2023 |
| DEWright | 8 | Wright | Derek | ASSOCIATE;FORKLIFT OPERATOR | 12/13/2022 |

# 4HH

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

**Non-Refundable $1,000 Fee**

Rev (08/17/2022)

| **Where is the facility located?** | ☐ Nevada ■ Out-of-State |
|---|---|

| **Type of Application (check applicable box)** | | **Wholesaler Business Type (check applicable box)** |
|---|---|---|
| ■ New Wholesaler<br>☐ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH _____ | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: Skyline Pharmaceuticals, Inc

Physical Address: 3323 W Commercial Blvd #125

City: Ft Lauderdale State: FL Zip: 33309

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 888-517-3701 Website: www.skylinepharmaceuticals.com

Name of Designated Representative (DR): Christopher Lee

Licensing Company Email: info@skylinepharmaceuticals.co DR Email: info@skylinepharmaceuticals.com

| **Entities the Wholesaler will Serve (✓ all applicable)** | **Products to be Handled or Wholesaled (✓ all applicable)** | **Type of Wholesaling (✓ all applicable)** |
|---|---|---|
| ■ Pharmacies<br>■ Practitioners<br>■ Hospitals<br>☐ Wholesalers<br>☐ Veterinarians<br>☐ Others: | ■ Dangerous Drugs<br>☐ Controlled Substances<br>☐ [a]Medical devices, equipment, supplies, gases<br>☐ Others: | ☐ Manufacturer<br>☐ Repacker<br>☐ Reverse Distributor<br>■ Warehouse<br>■ Retail pharmacy wholesale distributor<br>☐ Others: |

| **Section 2: History of Company** | **Yes** | **No** |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✓ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | ✓ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | ✓ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✓ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✓ |

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

**Section 4: Publicly Traded Corporation**

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: Florida

Parent Company (if any): _____

Corporation/Organization Name: Skyline Pharmaceuticals, Inc

Mailing Address: 3323 W Commercial Blvd #125

City: Ft Lauderdale State: FL Zip: 33309

Telephone: 888-517-3701 Email: info@skylinepharmaceuticals.com

Contact Person Name: Christopher Lee

**Section 6: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

**Section 7: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Skyline Pharmaceuticals, Inc

Facility Name

Christopher Lee

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

04/13/2023

Date

| Board Use Only | Date Received: 4-17-23 | Amount: 1000.00 CK-3838 |
|---|---|---|

SKYLINE
PHARMACEUTICALS

# OFFICER & DIRECTOR ORGANIZATIONAL CHART

Skyline Pharmaceuticals, Inc
3323 W Commercial Blvd #125 Ft Lauderdale, FL 33309

1. Christopher Lee – President – 100% Ownership
2. Jennifer Lee – Director of Operations – 0% Ownership

SKYLINE
PHARMACEUTICALS

## CONTACT & PERCENTAGE OF OWNERSHIP INFORMATION

**Name and Title:** Christopher Lee – President
**Date of Birth:** [redacted]
**SSN:** [redacted]
**Percentage of Ownership:** 100%
**Address:** [redacted]riny Ave Pompano Beach, FL 33062
**Phone Number:** [redacted]
**Email:** info@skylinepharmaceuticals.com

SKYLINE
PHARMACEUTICALS

Chris Lee is responsible for the data maintenance of all prescription drugs that Skyline Pharmaceuticals buys, inventories, and sells. He takes care of the D.S.C.S.A. requirements associated with the transfer in and transfer out of prescription drugs as well as handles all recalls, quarantines, and customer complaints. Chris also handles the recruitment, hiring, and training of the Skyline Pharmaceuticals sales team. This includes but is not limited to payroll and HR as well.

3323 W. Commercial Blvd. Suite 125, Fort Lauderdale, FL 33309
(888)517-3701
www.skylinepharmaceuticals.com

# State of Florida
## Department of State

I certify from the records of this office that SKYLINE PHARMACEUTICALS, INC. is a corporation organized under the laws of the State of Florida, filed on March 5, 2010, effective March 1, 2010.

The document number of this corporation is P10000020023.

I further certify that said corporation has paid all fees due this office through December 31, 2023, that its most recent annual report/uniform business report was filed on February 28, 2023, and that its status is active.

I further certify that said corporation has not filed Articles of Dissolution.

*Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Sixth day of April, 2023*

*Secretary of State*

**Tracking Number: 2002134093CU**

**To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.**

**https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication**

Ron DeSantis, Governor

Melanie S. Griffin, Secretary

Florida dbpr

# STATE OF FLORIDA
# DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

## FLORIDA DRUGS, DEVICES AND COSMETICS

THE Prescription Drug Wholesale Distributor HEREIN HAS REGISTERED UNDER THE PROVISIONS OF CHAPTER 499, FLORIDA STATUTES

## SKYLINE PHARMACEUTICALS INC.

3323 WEST COMMERCIAL BOULEVARD
SUITE 125
FORT LAUDERDALE FL 33309

**LICENSE NUMBER: 2220303**

**EXPIRATION DATE: MARCH 31, 2025**

Always verify licenses online at MyFloridaLicense.com

Do not alter this document in any form.

This is your license. It is unlawful for anyone other than the licensee to use this document.

1378

FLORIDA DEPARTMENT of STATE DIVISION OF CORPORATIONS

Sunbiz.org DIVISION of CORPORATIONS
an official State of Florida website

Department of State / Division of Corporations / Search Records / Search by Entity Name /

Previous On List Next On List Return to List

skyline ph
Search

**No Events** **No Name History**

# Detail by Entity Name

Florida Profit Corporation
SKYLINE PHARMACEUTICALS, INC.

## Filing Information

| | |
|---|---|
| **Document Number** | P10000020023 |
| **FEI/EIN Number** | 27-2047911 |
| **Date Filed** | 03/05/2010 |
| **Effective Date** | 03/01/2010 |
| **State** | FL |
| **Status** | ACTIVE |

## Principal Address

3323 W. Commercial Blvd.
Suite 125
Fort Lauderdale, FL 33309

Changed: 03/08/2022

## Mailing Address

3323 W. Commercial Blvd.
Suite 125
Fort Lauderdale, FL 33309

Changed: 03/08/2022

## Registered Agent Name & Address

LEE, CHRISTOPHER P
3323 W. Commercial Blvd.
Suite 125
Fort Lauderdale, FL 33309

Address Changed: 02/28/2023

## Officer/Director Detail

**Name & Address**

Title P

LEE, CHRISTOPHER P
3323 W. Commercial Blvd.
Suite 125
Fort Lauderdale, FL 33309

## Annual Reports

| Report Year | Filed Date |
|---|---|
| 2021 | 02/04/2021 |
| 2022 | 03/08/2022 |
| 2023 | 02/28/2023 |

## Document Images

| | |
|---|---|
| 02/28/2023 -- ANNUAL REPORT | View image in PDF format |
| 03/08/2022 -- ANNUAL REPORT | View image in PDF format |
| 02/04/2021 -- ANNUAL REPORT | View image in PDF format |
| 04/27/2020 -- ANNUAL REPORT | View image in PDF format |
| 04/08/2019 -- ANNUAL REPORT | View image in PDF format |
| 04/03/2018 -- ANNUAL REPORT | View image in PDF format |
| 01/26/2017 -- ANNUAL REPORT | View image in PDF format |
| 03/04/2016 -- ANNUAL REPORT | View image in PDF format |
| 01/30/2015 -- ANNUAL REPORT | View image in PDF format |
| 01/09/2014 -- ANNUAL REPORT | View image in PDF format |
| 03/21/2013 -- ANNUAL REPORT | View image in PDF format |
| 04/09/2012 -- ANNUAL REPORT | View image in PDF format |
| 02/08/2011 -- ANNUAL REPORT | View image in PDF format |
| 03/05/2010 -- Domestic Profit | View image in PDF format |

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skyline ph
Search

No Events No Name History

SKYLINE
PHARMACEUTICALS

## EMPLOYEE LIST

Skyline Pharmaceuticals, Inc – FEIN #27-2047911
3323 W Commercial Blvd #125 Ft Lauderdale, FL 33309

1. Christopher Lee – President
2. Jennifer Lee – Director of Operations
3. Dana McDonald – Staff Accountant

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

### Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Skyline Pharmaceuticals, Inc

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 3323 W Commercial Blvd #125

City: Ft Lauderdale State: FL Zip: 33309

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 888-517-3701 Website: www.skylinepharmaceuticals.com

Licensing Company Email: info@skylinepharmaceuticals.com

### Section 2: Personal Information

First: Christopher Middle: Patrick Last: Lee

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Briny Ave

City: Pompano Beach State: FL Zip: 33062

Telephone: [redacted] Email: info@skylinepharmaceuticals.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| University of Florida | | 08/00-12/04 | |
| Address | City | State | Zip |
| 201 Criser Hall | Gainesville | FL | 32611 |
| Diploma/Degree obtained, if any | | | |
| Bachelors of Business and Sports Management | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Charles W. Flanagan High School | | 08/96-05/00 | |
| Address | City | State | Zip |
| 12800 Taft St | Pembroke Pines | FL | 33028 |
| Diploma/Degree obtained, if any | | | |
| High School Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 10/17-Present | [redacted]Briny Ave | Pompano Beach | FL | 33062 |
| 10/07-10/17 | [redacted]NE 27th St | Lighthouse Point | FL | 33064 |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
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| | | | | |
| | | | | |
| | | | | |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Skyline Pharmaceuticals, Inc | | | 03/10-Present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 3323 W Commercial Blvd #125 | | Ft Lauderdale | FL | 33309 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 888-517-3701 ext 1032 | President | | 27,144 | |
| **Description of Duties** | | | | |
| See attached. | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

Continue on next page if additional space is needed.

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | ✓ |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | | ✓ |
| 1. Copy of FDA registration<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** | | ✓ | | |
| • **List of all partners and their percent ownership.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✓ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✓ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✓ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

I, Christopher Lee, **certify that as the designated representative for**

Skyline Pharmaceuticals, Inc,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. CPL I am at least 21 years of age;
3. CPL I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CPL I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CPL I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CPL I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CPL I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Christopher Lee

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/13/2023

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Christopher Lee

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/13/2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of FLORIDA, ss. County of BROWARD

I, CHRISTOPHER LEE, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

4/13/23

**Date**

Subscribed and Sworn to before me this 13th day of APRIL 2023

**Notary Public Signature**

DANA MCDONALD
Commission # HH 256015
Expires August 21, 2026

**(Seal)**



# Christopher Lee

[redacted] Vest Commercial Blvd Ste [redacted]
Fort Lauderdale, FL 33309

[redacted]

chris@skylinepharmaceuticals.com

www.skylinepharmaceuticals.com

## Experience

**March 2010–Present**
Owner • President • Skyline Pharmaceuticals, Inc.

**March 2010–December 2021**
President of Sales • Gulf Coast Pharmaceuticals Plus LLC.

**January 2008–March 2010**
Sales Manager • MedSearch Inc.

Key responsibilities for MedSearch, Gulf Coast, and Skyline were, and are still, to Own or Manage, Operate, Administrate, Market, Train, and grow all companies successfully. While under my supervision, each entity blossomed into multi-million dollar enterprises that were at the top of each of their respective industries. My time at both MedSearch and Gulf Coast prepared me adequately to run Skyline with more knowledge of the industry and more equipped skillsets to lead my company.

Qualifications:
President of Sales and Owner of Skyline Pharmaceuticals which sells and services over 1500 Hospitals, Surgery Centers, Department of Defense, Veteran Affairs, EMS Fire, and Medical Facilities. I deal directly with pharmaceutical purchasers, nurses, physicians, directors of pharmacy, and patient advocates in order to help them receive timely medications that are in short supply when needed.

Job Duties:
Pharmacy Compliance, Warehousing, Hiring, Training, and Managing a staff of 30 that encompasses sales representatives, an in-house operations team, an in-house accounting team, and IT and website design. Things I directly oversee include all finances, business operations, contracts, policies and procedures, purchasing, invoicing, pedigree, T3-Data, Track and Trace, and the overall day-to-day operations of Skyline Pharmaceuticals.

## Education

**University of Florida, Gainesville, Florida** **2000-2004**

- 3.55 GPA. Business and Sports Management

## Certifications

Certified Drug Representative – CDR – Registered with the State of Florida - Status - Active **7/17/2013 - Present**

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/13/2022)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of Pharmacy/MDEG/Wholesaler: Skyline Pharmaceuticals, Inc

Pharmacy/MDEG/Wholesaler License # (if applicable):

Physical Address: 3323 W Commercial Blvd #125

City: Ft Lauderdale State: FL Zip: 33309

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 888-517-3701 Website: www.skylinepharmaceuticals.com

Licensing Company Email: info@skylinepharmaceuticals.com

**Section 2: Personal Information**

First: Christopher Middle: Patrick Last: Lee

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Briny Ave

City: Pompano Beach State: FL Zip: 33062

Telephone: [redacted] Email: info@skylinepharmaceuticals.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| University of Florida | | | 08/00-12/04 | |
| Address | | City | State | Zip |
| 201 Criser Hall | | Gainesville | FL | 32611 |
| Diploma/Degree obtained, if any | | | | |
| Bachelors of Business and Sports Management | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| Charles W. Flanagan High School | | | 08/96-05/00 | |
| Address | | City | State | Zip |
| 12800 Taft St | | Pembroke Pines | FL | 33028 |
| Diploma/Degree obtained, if any | | | | |
| High School Diploma | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |
| School Name | | | From - To (MM/YY – MM/YY | |
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 10/17-Present | [redacted] Briny Ave | Pompano Beach | FL | 33062 |
| 10/07-10/17 | [redacted] NE 27th St | Lighthouse Point | FL | 33064 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Skyline Pharmaceuticals, Inc | | | 03/10-Present |
| **Business Address** | **City** | **State** | **Zip** |
| 3323 W Commercial Blvd #125 | Ft Lauderdale | FL | 33309 |
| **Phone** | **Title** | | |
| 888-517-3701 ext 1032 | President | | |
| **Description of Duties** | | | |
| See attached. | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |
| | | | |

Continue on next page if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✓ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✓ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✓ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Christopher Lee

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/13/2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of FLORIDA, ss. County of BROWARD

I, CHRISTOPHER LEE, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

4/13/23

**Date**

Subscribed and Sworn to before me this 13th day of APRIL 2023

**Notary Public Signature**

DANA MCDONALD
Commission # HH 256015
Expires August 21, 2026

**(Seal)**

# NEVADA STATE BOARD OF PHARMACY

**431 W Plumb Lane**
**Reno, NV 89509**
**(775) 850-1440**
**Fax: (775) 850-1444**

## PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. TCS12533

Application/License No. _____

Skyline Pharmaceuticals Inc., doing or intending to do
Applicant/Principal
business as a pharmaceutical wholesaler, whose address for purposes of service is

3323 W Commercial Blvd Ste 125, Fort Lauderdale, FL 33309-3409, as
Address of Applicant/Principal
PRINCIPAL, and Hudson Insurance Company, a
Surety Company
corporation organized under the laws of the state of Delaware
State of Incorporation
and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is

100 William St Fl 5, New York, NY 10038-5044 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on March 17, 2023.
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.

(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.

(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.

(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.

(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.

(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.

(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 21st day of March, 20 23.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

Surety Company's Representative

Eric Fauerbach, Attorney-in-fact

print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A

Nevada Resident Agent

HUDSON INSURANCE GROUP

TCS12533

# POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That HUDSON INSURANCE COMPANY, a corporation of the State of Delaware, with offices at 100 William Street, New York, New York, 10038, has made, constituted and appointed, and by these presents, does make, constitute and appoint

Eric Fauerbach

**of the State of** South Carolina

its true and lawful Attorney(s)-in-Fact, at New York, New York, each of them alone to have full power to act without the other or others, to make, execute and deliver on its behalf, as Surety, bonds and undertakings given for any and all purposes, also to execute and deliver on its behalf as aforesaid renewals, extensions, agreements, waivers, consents or stipulations relating to such bonds or undertakings provided, however, that no single bond or undertaking shall obligate said Company for any portion of the penal sum thereof in excess of the sum of

One Hundred Thousand Dollars and Zero Cents

Such bonds and undertakings when duly executed by said Attorney(s)-in-Fact, shall be binding upon said Company as fully and to the same extent as if signed by the President of said Company under its corporate seal attested by its Secretary.

In Witness Whereof, HUDSON INSURANCE COMPANY has caused these presents to be of its Senior Vice President thereunto duly
d, on this 2nd day of June, 20 22 at New York, New York.
: seal)

**HUDSON INSURANCE COMPANY**

Attest.....
**Dina Daskalakis No. 01MU6067553**
Corporate Secretary

By.....
**Michael P. Cifone**
Senior Vice President

STATE OF NEW YORK
COUNTY OF NEW YORK. SS.

On the 2nd day of June, 20 22 before me personally came Michael P. Cifone to me known, who being by me duly sworn did depose and say that he is a Senior Vice President of **HUDSON INSURANCE COMPANY**, the corporation described herein and which executed the above instrument, that he knows the seal of said Corporation, that the seal affixed to said instrument is such corporate seal, that it was so affixed by order of the Board of Directors of said Corporation, and that he signed his name thereto by like order.

(Notarial Seal)

ANN M. MURPHY NOTARY PUBLIC STATE OF NEW YORK

.....
**ANN M. MURPHY**
Notary Public, State of New York
No. 01MU6067553
Qualified in Nassau County
Commission Expires December 10, 2025

## CERTIFICATION

STATE OF NEW YORK
COUNTY OF NEW YORK SS.

The undersigned **Dina Daskalakis** hereby certifies:

That the original resolution, of which the following is a true and correct copy, was duly adopted by unanimous written consent of the Board of Directors of Hudson Insurance Company dated July 27th, 2007, and has not since been revoked, amended or modified:

"RESOLVED, that the President, the Executive Vice Presidents, the Senior Vice Presidents and the Vice Presidents shall have the authority and discretion, to appoint such agent or agents, or attorney or attorneys-in-fact, for the purpose of carrying on this Company's surety business, and to empower such agent or agents, or attorney or attorneys-in-fact, to execute and deliver, under this Company's seal or otherwise, bonds obligations, and recognizances, whether made by this Company as surety thereon or otherwise, indemnity contracts, contracts and certificates, and any and all other contracts and undertakings made in the course of this Company's surety business, and renewals, extensions, agreements, waivers, consents or stipulations regarding undertakings so made; and

FURTHER RESOVLED, that the signature of any such Officer of the Company and the Company's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seal when so used whether heretofore or hereafter, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed."

THAT the above and foregoing is a full, true and correct copy of Power of Attorney issued by said Company, and of the whole of the original and that the said Power of Attorney is still in full force and effect and has not been revoked, and furthermore that the Resolution of the Board of Directors, set forth in the said Power of Attorney is now in force.

Witness the hand of the undersigned and the seal of said Corporation this 21st day of March, 20 23.

seal)

By.....
**Dina Daskalakis,** Corporate Secretary

# 411

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Pharmacy Application
## Non-Refundable $500.00 Fee

Rev (8/02/2022)

| Facility Location | Application Type (check all applicable) | Pharmacy Type (check all applicable) | Services the Pharmacy will Provide (check all applicable) |
|---|---|---|---|
| ☑ Nevada | ☑ New Pharmacy | ☑ Retail/Community | ☑ Retail/Community |
| ☐ Out-of-State | ☐ Ownership Change* | ☐ Hospital (# beds _____) | ☐ Non-sterile Compounding |
| | ☐ Location Change * | ☐ Internet | ☐ Sterile Compounding |
| | ☐ Name Change* | ☐ Nuclear | ☑ Mail-Order Service |
| | | ☐ Other: | ☑ Off-site Cognitive Services |
| | * If making a change, provide license #: | | ☑ Long Term Care |
| | | | ☑ Hospital |
| | PH_____ | | ☐ Other: |

| Days of Operation | | Ownership Type (check applicable box) |
|---|---|---|
| ☑ Monday | ☑ Friday | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12) |
| ☑ Tuesday | ☐ Saturday | ☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12) |
| ☑ Wednesday | ☐ Sunday | ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12) |
| ☑ Thursday | ☐ Holidays | ☑ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12) |

### Section 1: General Information

Pharmacy Name: Dignity Specialty Pharmacy

Physical Address: 3399 S Eastern Avenue # B

City: Las Vegas State: NV Zip: 89169

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 7252637099 N/A Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: _____ Contact Email: _____

Website: _____

Nevada Business License # (if applicable) NV20232844717

Supervising/Managing Pharmacist Name (NRS 639.220): Modupe Inonbeje

Supervising/Managing Pharmacist NV Pharmacist Registration #: 17933

**Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)**

| | |
|---|---|
| Name: Modupe Inuwobeje | NV Pharmacist Registration #: 17953 |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |

| Section 3: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✓ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction? | | ✓ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry? | | ✓ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✓ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✓ |

**If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.**

**Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)**

| | | |
|---|---|---|
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: N/A | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

## Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

## Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

## Section 7: Partnership

Partnership Name: _____

Mailing Address: N/A

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

## Section 8: Sole Owner

Owner's Name: Modupe Ibironbeye

Business Name: Dignity Specialty Pharmacy

Business Address: 3399 S Eastern Avenue #B

City: Las Vegas State: NV Zip: 89169

Telephone: 725 263 7099 Email: Dupelo@yahoo.com

## Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

### Statement of Responsibility

1. I am the Modupe Iromobeyi (title) for Dignity Specialty Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Modupe Iromobeyi

Print Name of Authorized Person

MIromobeyi

Original signature of Authorized Person (copies or stamps not accepted)

7/13/2023

Date

**Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding**

## Affidavit for Pharmacy License

I, Moduje Ivorobeji hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Manager (title) for Dignity Specialty Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 13 day of July, 2023

Nicole C. Pursell
Notary Public

NICOLE C PURSELL
Notary Public, State of Nevada
Appointment No. 23-8795-01
My Appt. Expires Jun 14, 2027

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Modupe Inumbeyi

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Inumbeyi

Original signature of Authorized Person (copies or stamps not accepted)

7/13/2023

Date

| Board Use Only | Date Received: 7/25/23 | Amount: 500-CK-0104 |
|---|---|---|

**Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY**

Managing Pharmacist Name: Modupe Inonbeje Pharmacist Registration #: 17933

Pharmacy Name: Dignity Specialty Pharmacy

**Initial each statement below to indicate you have read and agree with the following:**

MAI I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

MAI I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

MAI I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

MAI I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

MAI I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

| Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |
| 2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state? | | ✓ |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? | | ✓ |
| 4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state? | | ✓ |

**If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.**

| Board Administrative Action: | State: | Date: | Case #: |
|---|---|---|---|
| | | | |

| Criminal Action: | State: | Date: | Case #: | County: | Court: |
|---|---|---|---|---|---|
| | | | | | |

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

7/13/2023
Date

SECRETARY OF STATE

STATE OF NEVADA

# NEVADA STATE BUSINESS LICENSE

## DIGNITY SPECIALTY PHARMACY LLC

**Nevada Business Identification # NV20232844717**
**Expiration Date: 07/31/2024**

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
**License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.**

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 07/12/2023.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202307123802566
You may verify this certificate online at http://www.nvsos.gov

SECRETARY OF STATE

STATE OF NEVADA

# DOMESTIC LIMITED-LIABILITY COMPANY (86) CHARTER

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that **DIGNITY SPECIALTY PHARMACY LLC** did, on 07/12/2023, file in this office the original Articles of Organization that said document is now on file and of record in the office of the Secretary of State of the State of Nevada, and further, that said document contains all the provisions required by the law of the State of Nevada.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 07/12/2023.

FRANCISCO V. AGUILAR
Secretary of State

Certificate
Number: B202307123802565
You may verify this certificate online at http://www.nvsos.gov

SECRETARY OF STATE

STATE OF NEVADA

# CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporation soles, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify, that the following is a list of all organizational documents on file in this office for

DIGNITY SPECIALTY PHARMACY LLC

| Organizational Documents on File | Filing Date |
|---|---|

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, DIGNITY SPECIALTY PHARMACY LLC, as a corporation duly organized under the laws of Nevada and existing under and by virtue of the laws of the State of Nevada since 07/12/2023, and is in good standing in this state.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 07/12/2023

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202307123802588
You may verify this certificate online at http://www.nvsos.gov

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

**Section 1: Pharmacy/Wholesaler Information**

Name of Pharmacy/Wholesaler Dignity Specialty Pharmacy

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 3399 S Eastern Ave #B

City Las Vegas State NV Zip 89169

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 7252637099 Website N/A

Licensing Company Email _____

**Section 2: Personal Information**

First Modupe Middle Ajoke Last Ivoroboje

Alias(es, nicknames, name changes, etc.) Braithwaite

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted] Kilkenan Ct

City Las Vegas State NV Zip 89141

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✓ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Maryland Comprehensive high School | | 1991 – 1997 | |
| Address | City | State | Zip |
| Maryland Lagos, Nigeria | Lagos | Lagos | Nigeria |
| Diploma/Degree obtained, if any | | | |
| High School Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Florida Memorial University | | 02/2003 – 05/2007 | |
| Address | City | State | Zip |
| 15800 NW 42 Avenue | Miami Gardens | FL | 33054 |
| Diploma/Degree obtained, if any | | | |
| Bachelor of Science | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Roseman College of Health Sciences | | 06/2007 – 06/2010 | |
| Address | City | State | Zip |
| 11 Sunset Way | Henderson | NV | 89014 |
| Diploma/Degree obtained, if any | | | |
| Pharm D | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 12/2017 – Present | [redacted] Kilkenny Ct. | Las Vegas | NV | 89141 |
| 05/2011 – 12/2017 | [redacted] Tundra Swan St | Las Vegas | NV | 89122 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above:**

| | | | |
|---|---|---|---|
| Business Name: Elevance Health | | | From - To (MM/YY – MM/YY): 10/2020 – Present |
| Business Address: 740 W Peachtree St | City: Atlanta | State: GA | Zip: 30308 |
| Phone: 800 232 0113 | Title: Clinical Pharmacist Consultant | Number of Employed Hours: 6720 | |
| Description of Duties: Medication Management, Patient counselling | | | |

| | | | |
|---|---|---|---|
| Business Name: Montevista Hospital | | | From - To (MM/YY – MM/YY): 05/2019 - 05/2020 |
| Business Address: 5900 W Rochelle ave | City: Las vegas | State: NV | Zip: 89102 |
| Phone: 702 364 1111 | Title: Pharmacy Manager | Number of Employed Hours: 2240 | |
| Description of Duties: Filling Prescriptions, verifying prescriptions, Pharmacy antibiotic / P&T Committee, Purchasing, Storage Program | | | |

| | | | |
|---|---|---|---|
| Business Name: Providence Pharmacy #F | | | From - To (MM/YY – MM/YY): 10/2013 – 03/2019 |
| Business Address: 1729 E Charleston Blvd | City: Las vegas | State: NV | Zip: 89104 |
| Phone: 702 778 3072 | Title: Pharmacy Manager | Number of Employed Hours: 11,500 | |
| Description of Duties: Oversee all Pharmacy operations dispensing, Storage, filling prescriptions, Inventory control | | | |

| | | | |
|---|---|---|---|
| Business Name: | | | From - To (MM/YY – MM/YY): |
| Business Address: | City: | State: | Zip: |
| Phone: | Title: | Number of Employed Hours: | |
| Description of Duties: | | | |

| | | | |
|---|---|---|---|
| Business Name: | | | From - To (MM/YY – MM/YY): |
| Business Address: | City: | State: | Zip: |
| Phone: | Title: | Number of Employed Hours: | |
| Description of Duties: | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | N/A |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✓ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✓ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✓ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| N/A |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

I, Modupe Inonbeje, **certify that as the designated representative for** Dignity Specialty Pharmacy,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. MAE I am at least 21 years of age;
3. MAE I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MAE I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MAE I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MAE I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MAE I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Modupe Inonbeje

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/13/2023

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Modupe Irorobeji
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/13/2023
Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Nevada, ss. County of Clark

I, Modupe Irorobeji, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

7/13/2023
**Date**

Subscribed and Sworn to before me this 13 day of July.

Nicole C. Pursell
**Notary Public Signature**

NICOLE C PURSELL
Notary Public, State of Nevada
Appointment No. 23-8795-01
My Appt. Expires Jun 14, 2027

**(Seal)**

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/18/2023)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Dignity Specialty Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 3899 S Eastern Avenue #B

City Las Vegas State NV Zip 89169

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 725 263 7099 Website N/A

Licensing Company Email _____

**Section 2: Personal Information**

First Modupe Middle Ajoke Last Irorobeje

Alias(es, nicknames, name changes, etc.) Braithwaite

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted] Kilkenny Ct

City Las Vegas State NV Zip 89141

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✓ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | From - To (MM/YY – MM/YY) |
|---|---|
| Roseman College of Health Sciences | 08/2007 – 06/2010 |

| Address | City | State | Zip |
|---|---|---|---|
| 11 Sunset Way | Henderson | NV | 89014 |

Diploma/Degree obtained, if any: PharmD

| School Name | From - To (MM/YY – MM/YY) |
|---|---|
| Florida Memorial University | 08/2003 – 05/2007 |

| Address | City | State | Zip |
|---|---|---|---|
| 15800 NW 42 Ave | Miami Gardens | FL | 33054 |

Diploma/Degree obtained, if any: Bachelor of Science in Biology

| School Name | From - To (MM/YY – MM/YY) |
|---|---|
| Maryland Comprehensive high School | |

| Address | City | State | Zip |
|---|---|---|---|
| Lagos Nigeria | Lagos | Lagos | Nigeria |

Diploma/Degree obtained, if any: High School Diploma

| School Name | From - To (MM/YY – MM/YY) |
|---|---|
| | |

| Address | City | State | Zip |
|---|---|---|---|
| N/A | | | |

Diploma/Degree obtained, if any:

| School Name | From - To (MM/YY – MM/YY) |
|---|---|
| | |

| Address | City | State | Zip |
|---|---|---|---|
| N/A | | | |

Diploma/Degree obtained, if any:

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 12/2017 – Present | [redacted] Kilkerran ct | Las Vegas | NV | 89141 |
| 05/2011 – 12/2017 | [redacted] tundra swan st. | Las Vegas | NV | 89122 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| | | | | |
|---|---|---|---|---|
| Business Name: Elevance Health | | | From - To (MM/YY – MM/YY): 10/2020 – Present | |
| Business Address: 740 W Peachtree St | City: Atlanta | State: GA | Zip: 30308 | |
| Phone: 800-232-0113 | Title: Clinical Pharmacist Consultant | | | |
| Description of Duties: Medication Management therapy Patient Counseling | | | | |

| | | | | |
|---|---|---|---|---|
| Business Name: Montevista Hospital | | | From - To (MM/YY – MM/YY): 05/2019 – 05/2020 | |
| Business Address: 5900 W Rochelle Ave | City: Las Vegas | State: NV | Zip: 89103 | |
| Phone: 702 364 1111 | Title: Pharmacy Manager | | | |
| Description of Duties: Purchasing, Storage, dispensing, verifying prescriptions, P&T Committee, Antibiotic Stewardship Program | | | | |

| | | | | |
|---|---|---|---|---|
| Business Name: Providence Pharmacy | | | From - To (MM/YY – MM/YY): 10/2013 – 03/2019 | |
| Business Address: 1729 E Charleston Blvd | City: Las Vegas | State: NV | Zip: 89104 | |
| Phone: 702-778 3072 | Title: Pharmacy Manager | | | |
| Description of Duties: | | | | |

| | | | | |
|---|---|---|---|---|
| Business Name: | | | From - To (MM/YY – MM/YY): | |
| Business Address: | City: | State: | Zip: | |
| Phone: | Title: | | | |
| Description of Duties: | | | | |

| | | | | |
|---|---|---|---|---|
| Business Name: | | | From - To (MM/YY – MM/YY): | |
| Business Address: | City: | State: | Zip: | |
| Phone: | Title: | | | |
| Description of Duties: | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations: | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✓ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✓ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✓ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✓ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | N/A | | |
| **Reason/Charge** | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| **Name of Business/Industry/Entity** | | | | |

**Provide explanation below:**

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Modupe Ironbeji

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/13/2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Nevada, ss. County of Clark

I, Modupe Ironbeji, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

7/13/2023

**Date**

Subscribed and Sworn to before me this 13 day of July.

Nicole C Pursell

**Notary Public Signature**

NICOLE C PURSELL
Notary Public, State of Nevada
Appointment No. 23-8795-01
My Appt. Expires Jun 14, 2027

**(Seal)**

# 4JJ

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Pharmacy Application

**Non-Refundable $500.00 Fee**

Rev (8/02/2022)

| Facility Location | Application Type (check all applicable) | Pharmacy Type (check all applicable) | Services the Pharmacy will Provide (check all applicable) |
|---|---|---|---|
| ■ Nevada<br>☐ Out-of-State | ■ New Pharmacy<br>☐ Ownership Change*<br>☐ Location Change *<br>☐ Name Change*<br><br>* If making a change, provide license #:<br><br>PH_____ | ☐ Retail/Community<br>☐ Hospital (# beds _____)<br>☐ Internet<br>☐ Nuclear<br>■ Other:<br>Free-Standing Emergency Department. A unit of Northern Nevada Sierra Medical Center. | ☐ Retail/Community<br>☐ Non-sterile Compounding<br>☐ Sterile Compounding<br>☐ Mail-Order Service<br>☐ Off-site Cognitive Services<br>☐ Long Term Care<br>☐ Hospital<br>■ Other:<br>Free-Standing ED |

| Days of Operation | | Ownership Type (check applicable box) |
|---|---|---|
| ■ Monday | ■ Friday | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12) |
| ■ Tuesday | ■ Saturday | ☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12) |
| ■ Wednesday | ■ Sunday | ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12) |
| ■ Thursday | ■ Holidays | ■ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12) |

### Section 1: General Information

Pharmacy Name: ER at Damonte Ranch, an Extension of Northern Nevada Sierra Medical Center

Physical Address: 1041 Steamboat Parkway

City: Reno State: NV Zip: 89521

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: _____ Contact Email: kala.squires@uhsinc.com

Website: _____

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Kala Squires

Supervising/Managing Pharmacist NV Pharmacist Registration #: 17176

**Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)**

| | |
|---|---|
| Name: Amy Ryan | NV Pharmacist Registration #: 16551 |
| Name: Cassie Musick | NV Pharmacist Registration #: 18528 |
| Name: Taylor Sikkenga | NV Pharmacist Registration #: 20606 |
| Name: Mercylyn Kosel | NV Pharmacist Registration #: 18602 |
| Name: Kevin Flynn | NV Pharmacist Registration #: 17333 |
| Name: Brian McFadden | NV Pharmacist Registration #: 20659 |
| Name: Iris Li | NV Pharmacist Registration #: 20302 |
| Name: Kathleen Huynh | NV Pharmacist Registration #: 19754 |
| Name: Jacqueline Rai | NV Pharmacist Registration #: 18719 |
| Name: Benjamin Rok | NV Pharmacist Registration #: 17414 |
| Name: Lara May | NV Pharmacist Registration #: 17646 |

| Section 3: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✓ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction? | | ✓ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry? | | ✓ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✓ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✓ |

**If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.**

**Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)**

| | | |
|---|---|---|
| Name: N/A | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

**Section 5: Publicly Traded Corporation**

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 6: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 7: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 8: Sole Owner**

Owner's Name: Sparks Family Hospital

Business Name: Northern Nevada Sierra Medical Center

Business Address: 6500 Longley LN

City: Reno State: NV Zip: 89511

Telephone: 775-799-7320 Email: _____

**Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)**

**Statement of Responsibility**

1. I am the Managing Pharmacist (title) for ER at Damonte Ranch, an Extension of NNSMC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Kala Squires

Print Name of Authorized Person

Kala Squires

Original signature of Authorized Person (copies or stamps not accepted)

7/18/23

Date

**Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding**

## Affidavit for Pharmacy License

I, Kala Squires hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Managing Pharmacist (title) for ER at Damonte Ranch, an Extension of NNSMC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Kala Squires
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 18th day of July, 2023

Notary Public

Corrie Roll
Notary Public, State of Nevada
My Commission Expires: 05-25-24
Certificate No: 08-7370-3

State of Nevada
County of ~~Carson City~~ Washoe
This instrument was acknowledged
before me on: 7-18-23 by: Kayla D. Squires

**Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY**

Managing Pharmacist Name: Kala Squires Pharmacist Registration #: 17176

Pharmacy Name: ER at Damonte Ranch, an Extension of NNSMC

**Initial each statement below to indicate you have read and agree with the following:**

KS I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

KS I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

KS I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

KS I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

KS I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

| Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |
| 2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state? | | ✓ |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? | | ✓ |
| 4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state? | | ✓ |

**If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.**

| Board Administrative Action: | State: | Date: | Case #: |
|---|---|---|---|
| | | | |

| Criminal Action: | State: | Date: | Case #: | County: | Court: |
|---|---|---|---|---|---|
| | | | | | |

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kala Squires
Original signature of Managing Pharmacist (copies or stamps not accepted)

7/18/23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kala Squires

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Kala Squires — 7/18/23

Original signature of Authorized Person (copies or stamps not accepted) — Date

| Board Use Only | Date Received: 7/18/23 | Amount: 500-CC |
|---|---|---|

FILED

JUN 01 2023

JANIS GALASSINI
WASHOE COUNTY CLERK
BY _____ DEPUTY

**CORPORATION, LLC, BUSINESS TRUST & LEGAL ENTITIES**
CERTIFICATE OF BUSINESS: FICTITIOUS FIRM NAME
* * **THIS CERTIFICATE EXPIRES:* 5/31/28 * * *
*(OFFICE USE ONLY)*

◯ Renewal ◉ New Filing *Contact Number:* (610) 768-3300 *Email:* uhscorpfilings@uhsinc.com

THE UNDERSIGNED does hereby certify that IT IS
conducting a free-standing emergency room business at
1041 Steamboat Parkway (Physical street address), Reno (City), NV (State) 89521 (Zip code)
under the fictitious firm name of: ER at Damonte Ranch, an Extension of Northern Nevada Sierra Medical Center
and that said firm is composed of the following *legal entity* (or entities)* whose mailing address, signing officer's name, and title are as follows:

*Legal Entity Name:* Sparks Family Hospital, Inc.
(Legal entity must state name exactly as it is on file in State of Nevada)

*Entity Physical Address:* 367 S Gulph Rd (Physical street address), King of Prussia (City), PA (State), 19406 (Zip code)

*Signing Officer Name:* Steve Filton

*Signing Officer Title:* Vice President

***FOR ADDITIONAL OWNERS, PLEASE USE ADDITIONAL PAGES***

*Alternate Mailing Address:* _____ (P.O. Box or Physical street address other than listed above), _____ (City), _____ (State), _____ (Zip code)

*Prior Related DBA Filing (if applicable):* _____

WITNESS my hand this 25th day of May, 20 23.

*The undersigned hereby swears under penalty of perjury that he/she has authority to sign on behalf of and to bind the above-named legal entity to a contract.*

X _____
Signature of authorized officer

STATE OF Pennsylvania }
COUNTY OF Montgomery } ss.

On this 25th day of May, 2023 personally appeared before me, a Notary Public,
Steve Filton
(Name of individual whose signature is being notarized)
who acknowledged that he/she executed the above instrument.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official stamp at my office in the County of Montgomery the day and year in this certificate first above written.

_____
Signature of Notary Public

For office use only

IF SUBMITTING A NOTARIZED DOCUMENT, PLEASE PROVIDE AN ORIGINAL AND 3 COPIES, A SELF-ADDRESSED STAMPED ENVELOPE AND $25.00 FILING FEE TO:
WASHOE COUNTY CLERK
1001 E. Ninth St., Bldg. A
RENO, NV 89512

Commonwealth of Pennsylvania - Notary Seal
DOUGLAS R. TEWKSBURY, Notary Public
Montgomery County
My Commission Expires October 25, 2024
Commission Number 1301489

177263

***FRANCISCO V. AGUILAR***
*Secretary of State*

***GABRIEL DI CHIARA***
*Chief Deputy*

**STATE OF NEVADA**

**OFFICE OF THE**
**SECRETARY OF STATE**

*Commercial Recordings & Notary Division*
*202 N. Carson Street*
*Carson City, NV 89701*
*Telephone (775) 684-5708*
*Fax (775) 684-7138*

*North Las Vegas City Hall*
*2250 Las Vegas Blvd North, Suite 400*
*North Las Vegas, NV 89030*
*Telephone (702) 486-2880*
*Fax (702) 486-2888*

UHS of Delaware
367 S. Gulph Road
King of Prussia, PA 19406, USA

**Work Order #:** W2023052401381
May 24, 2023
Receipt Version: 1

**Special Handling Instructions:**

**Submitter ID:** 40412

**Charges**

| Description | Fee Description | Filing Number | Filing Date/Time | Filing Status | Qty | Price | Amount |
|---|---|---|---|---|---|---|---|
| Certificates | Fees | 20233218126 | 5/24/2023 1:52:25 PM | Approved | 1 | $50.00 | $50.00 |
| Total | | | | | | | $50.00 |

**Payments**

| Type | Description | Payment Status | Amount |
|---|---|---|---|
| Credit Card | 6849615349146398203259 | Success | $50.00 |
| Total | | | $50.00 |

**Credit Balance:** $0.00

UHS of Delaware
367 S. Gulph Road
King of Prussia, PA 19406, USA

SECRETARY OF STATE

STATE OF NEVADA

# CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **SPARKS FAMILY HOSPITAL, INC.**, as a DOMESTIC CORPORATION (78) duly organized under the laws of Nevada and existing under and by virtue of the laws of the State of Nevada since 04/06/1979, and is in good standing in this state.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 05/24/2023.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202305243675976
You may verify this certificate online at http://www.nvsos.gov

# 4KK

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Pharmacy Application

## Non-Refundable $500.00 Fee

Rev (8/02/2022)

| Facility Location | Application Type (check all applicable) | Pharmacy Type (check all applicable) | Services the Pharmacy will Provide (check all applicable) |
|---|---|---|---|
| ■ Nevada | ■ New Pharmacy | ■ Retail/Community | ■ Retail/Community |
| ☐ Out-of-State | ☐ Ownership Change* | ☐ Hospital (# beds _____) | ■ Non-sterile Compounding |
| | ☐ Location Change * | ☐ Internet | ☐ Sterile Compounding |
| | ☐ Name Change* | ☐ Nuclear | ■ Mail-Order Service |
| | | ☐ Other: | ☐ Off-site Cognitive Services |
| | * If making a change, provide license #: | | ■ Long Term Care |
| | | | ☐ Hospital |
| | PH_____ | | ☐ Other: |

| Days of Operation | | Ownership Type (check applicable box) |
|---|---|---|
| ■ Monday | ■ Friday | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12) |
| ■ Tuesday | ■ Saturday | ■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12) |
| ■ Wednesday | ☐ Sunday | ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12) |
| ■ Thursday | ☐ Holidays | ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12) |

## Section 1: General Information

Pharmacy Name: Sky Vista Pharmacy

Physical Address: 5243 W Charleston Blvd #1

City: Las Vegas State: NV Zip: 89146

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (702) 241-7504 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: _____ Contact Email: bsr3051@gmail.com

Website: _____

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Rajendra Bhandari

Supervising/Managing Pharmacist NV Pharmacist Registration #: 13786

**Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)**

| | |
|---|---|
| Name: Rajendra Bhandari | NV Pharmacist Registration #: 13786 |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |

| Section 3: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✔ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction? | | ✔ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry? | | ✔ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✔ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✔ |

**If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.**

**Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)**

| | | |
|---|---|---|
| Name: N/A | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

## Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

## Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Bhandari LLC

Parent Company (if any): _____

Corporation/Organization Name: Bhandari LLC DBA Sky Vista Pharmacy

Mailing Address: 358 Newcastle Bridge Court

City: Las Vegas State: NV Zip: 89138

Telephone: (702) 241-7504 Email: bsr3051@gmail.com

Contact Person Name: Rajendra Bhandari

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

## Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

## Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

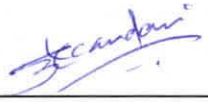
## Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

### Statement of Responsibility

1. I am the Pharmacy Manager (title) for Sky Vista Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Rajendra Bhandari

Print Name of Authorized Person



Original signature of Authorized Person (copies or stamps not accepted)

05/27/2023

Date

**Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding**

## Affidavit for Pharmacy License

I, Rajendra Bhandari hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacy Manager/Owner (title) for Sky Vista Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

BETSY KAIU LINDSEY-ESPANIOLA
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 10-30-25
Certificate No: 21-2456-01

SUBSCRIBED AND SWORN TO
Before me, a notary public this 22 day of June, 2023

Notary Public

**Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY**

Managing Pharmacist Name: Rajendra Bhandari Pharmacist Registration #: 13786

Pharmacy Name: Sky Vista Pharmacy

**Initial each statement below to indicate you have read and agree with the following:**

RB I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

RB I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

RB I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

RB I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

RB I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

| Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |
| 2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state? | | ✔ |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? | | ✔ |
| 4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state? | | ✔ |

**If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.**

| Board Administrative Action: | State: | Date: | Case #: |
|---|---|---|---|
| | | | |

| Criminal Action: | State: | Date: | Case #: | County: | Court: |
|---|---|---|---|---|---|
| | | | | | |

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

05/27/2023
Date

| Section 12: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)** | ✓ | ✓ | | |
| • **List the top four stockholders and their percent ownership. NRS 639.231(3)** | ✓ | ✓ | | |
| • **List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)** | | ✓ | | |
| • **For General Partnerships, list the name of each partner. NAC 639.214(2)**<br>• **For Limited Partnerships, list the names of (NAC 639.214(3)):**<br>o **All General Partners;**<br>o **All Limited Partners who hold 10% or more of the interest.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** from the Secretary of State's Office where the business is domiciled, dated within the last **6 months.** | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative Form** http://bop.nv.gov/Services/newapps/Business/ must be completed by the Designated Representative. NAC 639.5005. The requirement does not apply to:<br>a. An applicant or a licensee that is a publicly traded corporation;<br>b. An applicant or licensee whose pharmacy is determined by the Board to be located within a large retail store, including, without limitation, a grocery store, variety store or department store under common ownership; or<br>c. An applicant or licenses in which a majority interest of the applicant or licensee is owned by a pharmacist who is:<br>1) License by the Board; and<br>2) A resident of this state. | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** http://bop.nv.gov/Services/newapps/Business/ must be completed by:<br>a. **For Non-publicly traded -** The top 4 shareholder/stockholders.<br>b. **For Partnerships -** All general partners; all limited partners who hold 10% or more of the interest.<br>c. **For Sole Owner** - The owner. | | ✓ | ✓ | ✓ |
| • **Sterile Compounding Questionnaire** must be completed if the pharmacy will provide sterile compounded drugs. Access form at http://bop.nv.gov/Services/newapps/Business/. | ✓ | ✓ | ✓ | ✓ |
| • **Submit a copy of your most recent pharmacy inspection** from the regulatory or licensing authority of the state, territory or Federal agency in which the pharmacy is located. **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2328(2)(f) | ✓ | ✓ | ✓ | ✓ |
| • **Submit a copy of your license, certification, permit or registration issued to your pharmacy** from the regulatory board or licensing authority of the state or territory in which the pharmacy is located. **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2328(2)(a) | ✓ | ✓ | ✓ | ✓ |
| • **License Verification** by the regulatory board or licensing authority of the state or territory in which the pharmacy is located. You may use the License Verification form here: http://bop.nv.gov/Services/newapps/Business/. **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2238(2)(g) | ✓ | ✓ | ✓ | ✓ |
| • **Copy of DEA Registration if handling controlled substances (REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** | ✓ | ✓ | ✓ | ✓ |
| • **Internet Pharmacy Services Certification (REQUIRED FOR PHARMACIES PROVIDING INTERNET PHARMACY SERVICES)** | ✓ | ✓ | ✓ | ✓ |
| • **Transmit Controlled Substance Prescription Data-** Pharmacies dispensing scheduled II-V controlled substance for human consumption shall, not later than the end of the next business day after dispensing a controlled substance, upload to the Nevada Prescription Monitoring Program (PMP) the information described in paragraph (d) of subsection 1 of NRS 453.162. Registration information found at: https://bop.nv.gov/links/PMP/ | ✓ | ✓ | ✓ | ✓ |

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Rajendra Bhandari

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

05/27/2023

Date

| Board Use Only | Date Received: 6/26/23 | Amount: $200 CC |
|---|---|---|

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/18/2023)

### Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Sky Vista Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 5243 W Charleston Blvd # 1

City: Las Vegas State: NV Zip: 89146

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: (702) 241-7504 Website:

Licensing Company Email: bsr3051@gmail.com

### Section 2: Personal Information

First: Rajendra Middle: Last: Bhandari

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Newcastle Bridge Ct

City: Las Vegas State: NV Zip: 89138

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | From - To (MM/YY – MM/YY) | | |
|---|---|---|---|
| High School | 07/70-04/75 | | |
| **Address** | **City** | **State** | **Zip** |
| Dhule (India) | Dhule | MS | 424001 |
| **Diploma/Degree obtained, if any** | | | |
| High School | | | |

| School Name | From - To (MM/YY – MM/YY) | | |
|---|---|---|---|
| COLLEGE | 07/76 - 04/79 | | |
| **Address** | **City** | **State** | **Zip** |
| Dhule (India) | Dhule | MS | 424001 |
| **Diploma/Degree obtained, if any** | | | |
| Junior College | | | |

| School Name | From - To (MM/YY – MM/YY) | | |
|---|---|---|---|
| Pharmacy College | 07/80 - 4/83 | | |
| **Address** | **City** | **State** | **Zip** |
| Mumbai (india) | Mumbai | MS | 400001 |
| **Diploma/Degree obtained, if any** | | | |
| Bachelor in Pharmacy | | | |

| School Name | From - To (MM/YY – MM/YY) | | |
|---|---|---|---|
| LIU University | 08/85 - 08/88 | | |
| **Address** | **City** | **State** | **Zip** |
| Brooklyn | New York | NY | 11201 |
| **Diploma/Degree obtained, if any** | | | |
| Master in Pharmacy (Industrial) | | | |

| School Name | From - To (MM/YY – MM/YY) | | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 12/03 - current | [redacted] Newcastle Bridge Court | Las Vegas | NV | 89138 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Red Rock Pharmacy | | | 09/12 - 11/16 |
| **Business Address** | **City** | **State** | **Zip** |
| 5243 W Charleston Blvd #4 | Las Vegas | NV | 89146 |
| **Phone** | **Title** | | |
| (702) 241-7504 | Pharmacy Manager/Owner | | |
| **Description of Duties** | | | |
| Managing the pharmacy | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| CVS Pharmacy | | | 09/11 - 03/12 |
| **Business Address** | **City** | **State** | **Zip** |
| 4800 W Charleston Blvd | Las Vegas | NV | 89146 |
| **Phone** | **Title** | | |
| (702) 877-9026 | Pharmacist/Pharmacy Manager | | |
| **Description of Duties** | | | |
| Managing the pharmacy | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Savon Pharmacy | | | 04/00 - 09/11 |
| **Business Address** | **City** | **State** | **Zip** |
| 7350 S Rainbow Blvd | Las Vegas | NV | 89139 |
| **Phone** | **Title** | | |
| (702) 739-1856 | Pharmacist/Pharmacy Manager | | |
| **Description of Duties** | | | |
| Managing the pharmacy | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |
| | | | |

Continue on next page if additional space is needed.

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations: | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question #** N/A **. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

N/A

Original Signature (electronic, copies or stamps not accepted)

06/29/2023

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Rajendra BHANDARI

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/29/2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Nevada, ss. County of Clark

I, ~~Amy Loera~~ Rajendra Bhandari being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

06/29/2023

**Date**

Subscribed and Sworn to before me this 29 day of June.

**Notary Public Signature**

AMY LOERA
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 07-06-26
Certificate No: 23-6919-01

**(Seal)**

SECRETARY OF STATE

STATE OF NEVADA

# NEVADA STATE BUSINESS LICENSE

**Bhandari LLC**

**Nevada Business Identification # NV20232817939**
**Expiration Date: 06/30/2024**

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
**License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.**

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 06/20/2023.

Certificate Number: B202306203737868
You may verify this certificate online at http://www.nvsos.gov

FRANCISCO V. AGUILAR
Secretary of State

FRANCISCO V. AGUILAR
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

# Initial List and State Business License Application - Continued

## Officers, Managers, Members, General Partners, Managing Partners or Trustees:

CORPORATION, INDICATE THE MANAGING MEMBER:

| Name | Country |
|---|---|
| Rajendra Bhandari | USA |

| Address | City | State | Zip/Postal Code |
|---|---|---|---|
| [redacted]Newcastle Bridge Ct | Las Vegas | NV | 89138 |

**None of the officers and directors identified in the list of officers has been identified with the fraudulent intent of concealing the identity of any person or persons exercising the power or authority of an officer or director in furtherance of any unlawful conduct.**

**I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the office of the Secretary of State.**

| X RAICH LAW PLLC | Representative | 06/19/2023 |
|---|---|---|
| **Signature of Officer, Manager, Managing Member, General Partner, Managing Partner, Trustee, Member, Owner of Business, Partner or Authorized Signer** *FORM WILL BE RETURNED IF UNSIGNED* | Title | Date |

# 4LL

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Pharmacy Application

**Non-Refundable $500.00 Fee**

Rev (8/02/2022)

| Facility Location | Application Type (check all applicable) | Pharmacy Type (check all applicable) | Services the Pharmacy will Provide (check all applicable) |
|---|---|---|---|
| ☐ Nevada<br>☒ Out-of-State | ☐ New Pharmacy<br>☒ Ownership Change*<br>☐ Location Change *<br>☒ Name Change*<br><br>* If making a change, provide license #:<br><br>PH 04110 | ☒ Retail/Community<br>☐ Hospital (# beds _____)<br>☐ Internet<br>☐ Nuclear<br>☐ Other: | ☒ Retail/Community<br>☒ Non-sterile Compounding<br>☐ Sterile Compounding<br>☒ Mail-Order Service<br>☐ Off-site Cognitive Services<br>☐ Long Term Care<br>☐ Hospital<br>☒ Other:<br>Veterinary Compounding |

| Days of Operation | | Ownership Type (check applicable box) |
|---|---|---|
| ☒ Monday | ☒ Friday | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12) |
| ☒ Tuesday | ☐ Saturday | ☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12) |
| ☒ Wednesday | ☐ Sunday | ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12) |
| ☒ Thursday | ☐ Holidays | ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12) |

### Section 1: General Information

Pharmacy Name: Brava CA LLC

Physical Address: 8 Digital Drive, Suite 104

City: Novato State: California Zip: 94949

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (415) 455-5590 Toll Free # (NAC 639.708, NRS 639.23286): (888) 855-6337

Fax: (415) 455-9039 Contact Email: brvlicensing@bluerabbit.vet

Website: www.bravacare.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Erik Clausen

Supervising/Managing Pharmacist NV Pharmacist Registration #: 21382

**Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)**

| | |
|---|---|
| Name: Erik Clausen | NV Pharmacist Registration #: 21382 |
| Name: Trisha Petticrew | NV Pharmacist Registration #: 23084 |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |

| Section 3: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✓ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction? | | ✓ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry? | | ✓ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✓ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✓ |

**If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.**

**Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)**

| | | |
|---|---|---|
| Name: NA | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

**Section 5: Publicly Traded Corporation**

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 6: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: Delaware

Parent Company (if any): GGVCP Holdco LLC

Corporation/Organization Name: Brava CA LLC

Mailing Address: 8 Digital Drive, Suite 104

City: Novato State: California Zip: 94949

Telephone: (415) 455-5590 Email: brvlicensing@bluerabbit.vet

Contact Person Name: Erik Calusen

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ■ No

**Section 7: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 8: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

**Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)**

## Statement of Responsibility

1. I am the President (title) for Brava CA LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Erik Clausen

Print Name of Authorized Person



Original signature of Authorized Person (copies or stamps not accepted)

6/2/23

Date

**Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding**

## Affidavit for Pharmacy License

I, Erik Clausen hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President (title) for Brava CA LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.



Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this _____ day of _____, 20_____

_____
Notary Public

SEE ATTACHED CALIFORNIA ALL PURPOSE JURAT

# CALIFORNIA JURAT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document, to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

STATE OF CALIFORNIA }

COUNTY OF Marin }

Subscribed and sworn to (or affirmed) before me on this 2 (Date) day of June (Month), 2023 (Year)

by Erik Matthew Clausen

*Name of Signers*

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

Signature: J. Forouzeh
*Signature of Notary Public*

JAFAR FOROUZEH
Notary Public - California
Marin County
Commission # 2371468
My Comm. Expires Aug 19, 2025

*Seal*
*Place Notary Seal Above*

**OPTIONAL**

*Though this section is optional, completing this information can deter alteration of the document or fraudulent attachment of this form to an unintended document.*

**Description of Attached Document**
Title or Type of Document: AFFidaviT

Document Date: 6/2/2023

Number of Pages: 10

Signer(s) Other Than Named Above:

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Erik Clausen

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

Date 6/2/23

| Board Use Only | Date Received: 6/7/23 | Amount: 500-CK-1333705 |
|---|---|---|

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

### Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Brava CA LLC

Pharmacy/Wholesaler License # (if applicable): PHY 58192 (CA)

Physical Address: 8 Digital Drive, Suite 104

City: Novato State: California Zip: 94949

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: (415) 455-5590 Website: www.bravacare.com

Licensing Company Email: brvlicensing@bluerabbit.vet

### Section 2: Personal Information

First: Erik Middle: Matthew Last: Clausen

Alias(es, nicknames, name changes, etc.): None

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]Zandra Place

City: Novato State: CA Zip: 94945

Telephone: [redacted] Email: erik.clausen@bluerabbit.vet

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✔ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| University of the Pacific | | 08/03 - 05/07 | |
| **Address** | **City** | **State** | **Zip** |
| 3601 Pacific Ave | Stockton | CA | 95211 |
| **Diploma/Degree obtained, if any** | | | |
| Doctor of Pharmacy with a Masters in Business Administration | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Montana State University | | 08/98 - 05/02 | |
| **Address** | **City** | **State** | **Zip** |
| Culbertson Hall, 100 | Bozeman | MT | 59717 |
| **Diploma/Degree obtained, if any** | | | |
| Bachelor of Science in Cell Biology and Neuroscience | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Whitefish High School | | 08/94 - 05/98 | |
| **Address** | **City** | **State** | **Zip** |
| 1143 4th St. | Whitefish | MT | 59937 |
| **Diploma/Degree obtained, if any** | | | |
| High School Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 08/15 - Present | [redacted] Zandra Place | Novato | CA | 94945 |
| 12/08 - 08/15 | [redacted] Marin Ave | Sausalito | CA | 94965 |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Brava CA LLC (formally known as Golden Gate Veterinary Compounding Pharmacy) | | | 10/08 - Present |
| **Business Address** | **City** | **State** | **Zip** |
| 8 Digital Drive, Suite 104 | Novato | CA | 94949 |
| **Phone** | **Title** | | **Number of Employed Hours** |
| 415-455-5590 | General Manager | | 27040 |
| **Description of Duties** | | | |
| Oversee all operations of the pharmacy including, but not limited to, oversight of all staff, ensuring compliance with all laws and regulations, and various other managerial duties on a day to day basis. | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | **Number of Employed Hours** |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | **Number of Employed Hours** |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | **Number of Employed Hours** |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | **Number of Employed Hours** |
| | | | |
| **Description of Duties** | | | |
| | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | ✔ | |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✔ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # 1 . **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| 11/21/1999 | 11/21/1999 | MT | Bozeman | Gallatin |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| TK-115-1999-35918 | Bozeman Municipal Court |

| Reason/Charge |
|---|
| Minor in Possession of Alcohol |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| Erik Clausen/State of Montana | N/A |

| Name of Business/Industry/Entity |
|---|
| N/A |

**Provide explanation below:**

The Incident occurred in November of 1999 in Bozeman, Montana. I was 20 years old at the time. I was a passenger in a car that was pulled over. All passengers were given a breathalyzer test, of which i failed. I was charged with Minor in Possession of Alcohol, which is a misdemeanor. I plead guilty to the charge and was assessed a fine of $80.

If the Board needs any further details of the incident, or has any questions, I can be contacted on my cell phone, which is (415) 601-8365, of by email at erik.clausen@bluerabbit.vet.

Original Signature (electronic, copies or stamps not accepted)

6/2/23
Date

I, Erik Clausen, **certify that as the designated representative for**

Brava CA LLC,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. e I am at least 21 years of age;
3. e I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. e I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. e I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. e I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. e I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Erik Clausen

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/2/23

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Erik Clausen

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/2/23

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of _____, ss. County of _____

I, ERIK CLAUSEN, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

6/2/23

**Date**

Subscribed and Sworn to before me this _____ day of _____.

**Notary Public Signature**

SEE ATTACHED CALIFORNIA ALL PURPOSE JURAT

**(Seal)**

# CALIFORNIA JURAT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document, to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

STATE OF CALIFORNIA }

COUNTY OF Marin }

Subscribed and sworn to (or affirmed) before me on this 2 (Date) day of June (Month), 2023 (Year)

by Erik Matthew Clausen

*Name of Signers*

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

Signature: J. Forouzeh
*Signature of Notary Public*

JAFAR FOROUZEH
Notary Public - California
Marin County
Commission # 2371468
My Comm. Expires Aug 19, 2025

*Seal*
*Place Notary Seal Above*

## OPTIONAL

*Though this section is optional, completing this information can deter alteration of the document or fraudulent attachment of this form to an unintended document.*

**Description of Attached Document**

Title or Type of Document: Application Certification

Document Date: 6/2/2023

Number of Pages: 9

Signer(s) Other Than Named Above:

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/13/2022)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of Pharmacy/MDEG/Wholesaler Brava CA LLC

Pharmacy/MDEG/Wholesaler License # (if applicable) _____

Physical Address 8 Digital Drive, Suite 104

City Novato State California Zip 94949

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (415) 455-5590 Website www.bravacare.com

Licensing Company Email brvlicensing@bluerabbit.vet

**Section 2: Personal Information**

First Erik Middle Matthew Last Clausen

Alias(es, nicknames, name changes, etc.) None

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]Zandra Place

City Novato State CA Zip 94945

Telephone [redacted] Email erik.clausen@bluerabbit.vet

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✔ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| University of the Pacific | | 08/03 - 05/07 | |
| **Address** | **City** | **State** | **Zip** |
| 3601 Pacific Ave | Stockton | CA | 95211 |
| **Diploma/Degree obtained, if any** | | | |
| Doctor of Pharmacy with a Masters in Business Administration | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Montana State University | | 08/98 - 05/02 | |
| **Address** | **City** | **State** | **Zip** |
| Culbertson Hall, 100 | Bozeman | MT | 59717 |
| **Diploma/Degree obtained, if any** | | | |
| Bachelor of Science in Cell Biology and Neuroscience | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Whitefish High School | | 08/94 - 05/98 | |
| **Address** | **City** | **State** | **Zip** |
| 1143 4th St. | Whitefish | MT | 59937 |
| **Diploma/Degree obtained, if any** | | | |
| High School Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 08/15 - Present | [redacted]Zandra Place | Novato | CA | 94945 |
| 12/08 - 08/15 | [redacted]Marin Ave | Sausalito | CA | 94965 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Brava CA LLC (formally known as Golden Gate Veterinary Compounding Pharmacy) | | | 10/08 - Present |
| **Business Address** | **City** | **State** | **Zip** |
| 8 Digital Drive, Suite 104 | Novato | CA | 94949 |
| **Phone** | **Title** | | |
| 415-455-5590 | General Manager | | |

Description of Duties

Oversee all operations of the pharmacy including, but not limited to, oversight of all staff, ensuring compliance with all laws and regulations, and various other managerial duties on a day to day basis.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |

Description of Duties

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |

Description of Duties

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |

Description of Duties

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |

Description of Duties

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations: | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | ✔ | |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✔ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # 1. **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| 11/21/1999 | 11/21/1999 | MT | Bozeman | Gallatin |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| TK-115-1999-35918 | Bozeman Municipal Court |

| Reason/Charge |
|---|
| Minor in Possession of Alcohol |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| Erik Clausen/State of Montana | N/A |

| Name of Business/Industry/Entity |
|---|
| N/A |

**Provide explanation below:**

The Incident occurred in November of 1999 in Bozeman, Montana. I was 20 years old at the time. I was a passenger in a car that was pulled over. All passengers were given a breathalyzer test, of which i failed. I was charged with Minor in Possession of Alcohol, which is a misdemeanor. I plead guilty to the charge and was assessed a fine of $80.

If the Board needs any further details of the incident, or has any questions, I can be contacted on my cell phone, which is (415) 601-8365, of by email at erik.clausen@bluerabbit.vet.



Original Signature (electronic, copies or stamps not accepted)

6/2/23

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Erik Clausen

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/2/23

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of California, ss. County of Marin

I, Erik Clausen, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

6/2/23

**Date**

Subscribed and Sworn to before me this 2 day of June, 2023

**Notary Public Signature**

SEE ATTACHED CALIFORNIA ALL PURPOSE JURAT

**(Seal)**

# CALIFORNIA JURAT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document, to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

STATE OF CALIFORNIA }

COUNTY OF Marin }

Subscribed and sworn to (or affirmed) before me on this 2 (Date) day of June (Month), 2023 (Year)

by Erik Matthew Clausen

*Name of Signers*

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

Signature: J. Forouzeh
*Signature of Notary Public*

JAFAR FOROUZEH
Notary Public - California
Marin County
Commission # 2371468
My Comm. Expires Aug 19, 2025

*Seal*
*Place Notary Seal Above*

## OPTIONAL

*Though this section is optional, completing this information can deter alteration of the document or fraudulent attachment of this form to an unintended document.*

**Description of Attached Document**
Title or Type of Document: Application Certification

Document Date: 6/2/2023

Number of Pages: 7

Signer(s) Other Than Named Above:

Date: 6/13/2019
Time: 11:11 AM
Page 1 of 1

**Bozeman Municipal Court**
Party Detail Summary
Criminal and Civil Cases

User: JNELSON

**Clausen, Erik M**

Balance due court: 0.00

**Case: TK-115-1999-35918** **Defendant** **Closed**
Judge: Karl P Seel Filing Date: 11/21/1999

| Charge | Degree | Disposed | Plea | Finding | Citation |
|---|---|---|---|---|---|
| **Possessing Beer Or Liquor While Under Age (** | | 11/22/1999 | Guilty | Guilty | 145222 |
| Issued: 11/21/1999 | Fines/Fees: | 80.00 | Paid: | 80.00 | Balance: 0.00 |
| | **Case Total:** | **80.00** | **Paid:** | **80.00** | **Balance: 0.00** |

I, Jamie Nelson, hereby certify that this is a true and correct copy of the original as the same appears in the files and records of the office of the Municipal Court of the City of Bozeman, County of Gallatin, State of Montana.

Dated the 14th day of June, 2019

Jamie Nelson

Bozeman Municipal Court Clerk

**NOTICE TO APPEAR AND COMPLAINT** ISSUED BY **BOZEMAN POLICE DEPARTMENT** 012A 145222

TE OF MONTANA / CITY OF BOZEMAN } VS.

DEFENDANT NAME: FIRST ERIK MIDDLE M. LAST CLAUSEN

STREET 1120 S 6TH

CITY Bozeman STATE MT ZIP 59715

SEX M WT 170 HT 603 EYES BLU HAIR BRO DOB [redacted]

D/L NO. [redacted] D/L STATE MT D/L EXP. YEAR 00

HO [redacted] EMPLOYER MSU-STUD BUSINESS PHONE

VEHICLE LICENSE NO. LIC. STATE MONTH YEAR

VEHICLE YEAR VEHICLE COLOR

VEHICLE MAKE

VEHICLE TYPE: ☐ CAR ☐ TRUCK ☐ PICKUP ☐ TRK/TRLR ☐ MOTORCYCLE

UNIFORM VIOLATION CODE 0021-0

DOCKET NUMBER (94) 3 5918

E DEFENDANT IS HEREBY GIVEN NOTICE TO APPEAR IN

☐ JUSTICE Rm 168 ☒ CITY Rm 123 ☐ YOUTH Rm 100

RT OF... CARLSON DEPT# ...

NTY OF GALLATIN

ATED AT 615 SOUTH 16TH (DOWNSTAIRS)

OZEMAN, MONTANA ON OR BEFORE

I AM MONDAY, WEDNESDAY OR THURSDAY

22 DAY OF NOV 99

NSWER THIS CHARGE.

IIS 22 DAY OF NOV 97

OMPLAINT WAS PRESENTED TO ME AND THE OFFICER OATH SWORE THAT THE CHARGES ARE TRUE.

Marilyn K Woods

Signature of Judge or Notary

TARY FOR THE STATE OF MONTANA
SIDING AT BOZEMAN, MONTANA
COMMISSION EXPIRES Sept 23-2000

**FAILURE TO APPEAR MAY RESULT IN A SUSPENSION OF YOUR DRIVER'S LICENSE OR PRIVILEGE TO DRIVE**

THE ABOVE NAMED DEFENDANT IS CHARGED WITH VIOLATING

☒ MONTANA CODE ☐ CITY CODE ☐ COUNTY ORDINANCE SECTION # 45-5-624

ON THE 21 DAY OF NOV 99 AT 0335 MILITARY TIME

IN THAT SAID DEFENDANT DID PURPOSELY OR KNOWINGLY OR NEGLIGENTLY

MINOR IN POSSESSION OF ALCOHOL (2ND)

PBT #10 .020 B.AC

NAMELY AT (LOCATION) 1300 W. COLLEGE

IF CHECKED ☐ PERSONAL APPEARANCE IN COURT REQUIRED ☐ BRING A PARENT

☒ BA TEST GIVEN ☐ ACCIDENT

RADAR UNIT NO. 24

BADGE NO. 152

BADGE NO. 151

SIGNATURE OF OFFICER

RECEIVED $ NONE AS APPEARANCE BOND

I, Janice Nelson, hereby certify that this is a true and correct copy of the original as the same appears in the files and records of the office of the Municipal Court of the City of Bozeman, County of Gallatin, State of Montana.

Dated the 14th day of June, 2019

Janice Nelson

Bozeman Municipal Court Clerk

STATE OF MONTANA,

Plaintiff,

v.

Erik Clausen Defendant.

CITY COURT OF THE CITY OF BOZEMAN
COUNTY OF GALLATIN, STATE OF MONTANA

**SENTENCING ORDER/ORDER OF COMMITMENT**

WHEREAS, on 11-22, 199 7 the above Defendant was ( ✓ ) arraigned in open Court ( ) video arraignment ( ✓ ) pled guilty ( ) convicted by jury ( ) convicted by judge, as set forth below, it is ORDERED that you, said Sheriff of Gallatin County take and receive the Defendant:

Cause No: 99-35918-MIP 2nd 1st

Bond: $ _____ cash / surety ☐ Defendant not to be released until bond paid ☐ Release immediately.

Sentence imposed:

☑ _____ months / year suspended/deferred sentence all but _____ hours / days incarceration to be served:

☐ Ineligible Work Program -- Unless indicated, defendant eligible for consideration for Work Program
☐ Credit for time served
☐ Incarceration immediate ☐ Incarceration in lieu of fines/costs/assessments of _____ days to serve in detention
☑ Fine of $ 50 + $5 and $15 administrative fees ☐ "No contact" Order entered by Court
☐ Witness/administrative fees/other court costs 70+10=80
☐ Community Service: Waived hours, must complete by _____ ☐ Time Pay
☐ ACT (alcohol) 1st 2nd 3rd ☐ ACT (drugs) 1st 2nd 3rd ☐ MIP (alcohol) 1st 2nd 3rd
☐ Probationary Driver's License is recommended by the Court.
☑ Other Book & release

**********

AS A PART OF YOUR SENTENCE, YOU SHALL:

☑ Obey all laws. ☐ Complete MIP Program. ☑ Notify Court of change of address/telephone number.
☑ Complete the Act/Drug Counseling Program & comply with recommendations of counselors.
☐ Complete minimum 25 hours Domestic Abuse Couseling within 6 months.
☐ Not drive until legally licensed to do so.
☐ Driver's license: ○ Surrendered ○ Lost per defendant ○ taken at Detention Center.
☐ License plates & registration suspended _____ Days.
☐ Surrender license plates & registration by _____.
☐ Re-enroll ACT/MIP/DRUG/Domestic Abuse/Additional Treatment/Community Service by _____.
☐ SHALL NOT consume alcohol or frequent any place whose primary purpose is to serve alcoholic beverages.
☐ SHALL NOT enter or be on the grounds of _____ for a period of _____ Months.
☑ COMPLY WITH COURT ORDERS. FAILURE TO APPEAR/PAY FINES/COMPLY MAY RESULT IN THE ISSUANCE OF A SUMMONS, ARREST WARRANT AND/OR SUSPENSION OF YOUR DRIVER'S LICENSE.

DONE AND ORDERED 11-22, 199 7.

PATRICIA KYLE CARLSON, Bozeman City Court Judge

I acknowledge that I will report to Detention Center by 4:00 pm on day of sentencing to make arrangements for jail sentence, and that I am to serve my time on 11-22, 199 7. I may not report while under the influence of alcohol.

Defendant's signature & date: 11-22, 199 7.

cc: ☐ Detention Center (original) ☐ Court ☐ Defendant ☐ Assistant City Attorney ☐ CONTINUED ON PAGE 2

NOTICE TO APPEAR AND COMPLAINT ISSUED BY BOZEMAN POLICE DEPARTMENT 012A 145222

E OF MONTANA / CITY OF BOZEMAN } VS.

DEFENDANT NAME: FIRST ERIK MIDDLE M. LAST CLAUSEN
STREET 1120 S 6TH
CITY Bozeman STATE MT ZIP 59715
SEX M WT 170 HT 603 EYES BLU HAIR BRO DOB [redacted]
D/L NO. [redacted] D/L STATE MT D/L EXP. YEAR 00
HOME PHONE [redacted] EMPLOYER MSU-STUD BUSINESS PHONE

VEHICLE LICENSE NO. LIC STATE MONTH YEAR
VEHICLE YEAR VEHICLE COLOR
VEHICLE MAKE
VEHICLE TYPE ☐ CAR ☐ TRUCK ☐ PICKUP ☐ TRAILER ☐ MOTORCYCLE

DOCKET NUMBER (99) 3598

E DEFENDANT IS HEREBY GIVEN
NOTICE TO APPEAR IN

☐ JUSTICE Rm 166 ☒ CITY Rm 123 ☐ YOUTH Rm 166

RT OF CARLSON DEPT#
NTY OF GALLATIN
ATED AT 615 SOUTH 15TH (DOWNSTAIRS)
OZEMAN MONTANA ON OR BEFORE
AM MONDAY, WEDNESDAY OR THURSDAY
22 DAY OF NOV 99
NSWER THIS CHARGE.

IS 22 DAY OF NOV 99
OMPLAINT WAS PRESENTED TO ME AND THE OFFICER
OATH SWORE THAT THE CHARGES ARE TRUE.
Signature of Judge or Notary

ARY FOR THE STATE OF MONTANA
IDING AT BOZEMAN, MONTANA
COMMISSION EXPIRES Sept 23-2000

FAILURE TO APPEAR MAY RESULT IN A SUSPENSION OF YOUR DRIVER'S LICENSE OR PRIVILEGE TO DRIVE

THE ABOVE NAMED DEFENDANT IS CHARGED WITH VIOLATING
☒ MONTANA CODE ☐ CITY CODE ☐ COUNTY ORDINANCE
SECTION # 45-5-624
ON THE 21 DAY OF NOV 99 AT 0335 MILITARY TIME
UNIFORM VIOLATION CODE 0021-0
IN THAT SAID DEFENDANT DID PURPOSELY OR KNOWINGLY OR NEGLIGENTLY
MINOR IN POSSESSION OF ALCOHOL (2ND)

PBT #1 D .020 B.A.C

NAMELY AT (LOCATION) 1300 W. COLLEGE

RECEIVED $ NONE AS APPEARANCE BOND

IF CHECKED ☐ PERSONAL APPEARANCE IN COURT REQUIRED DRING A PARENT
☒ B.A. TEST GIVEN ☐ ACCIDENT
RADAR UNIT NO. 24
BADGE NO. 152
BADGE NO. 157
SIGNATURE OF OFFICER

For [illegible] of the defendant to appear at the date fixed, [illegible] the amount of $ _____ is ordered forfeited.
On this 22nd day of November 1999
☐ IN CUSTODY ☐ WITH PARENT
defendant appeared, was advised of his constitutional rights, was arraigned, and entered a plea of 1st offense
Guilty
Fine: 40+154+10+10=80
Issued C/S
Def Booked + released
FINANCIAL RECORD $ 5 + 5 + 10 + 10
Amount Collected on Fines $ _____
Collection & Disbursement Journal Page _____ Date 11-22-99
TVD _____ 38689
CERTIFIED AND APPROVED
P Carlson
Justice of the Peace
or City Magistrate

# Delaware

The First State



*I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "BRAVA CA LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-FIRST DAY OF APRIL, A.D. 2023.*

*AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.*

Jeffrey W. Bullock, Secretary of State

5333065 8300

SR# 20231569711

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203191206

Date: 04-21-23

**California State Board of Pharmacy**
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

# INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 2/2/2023 Inspector: Denise Dukatz

Firm: BRAVA CA LLC Phone: ___

Address: 8 DIGITAL DR STE 104 City: NOVATO Zip: 94949

Ownership: CORPORATION

Permit #: PHY58192 Permit Exp: 5/1/2023 DEA#: FG0344767 DEA Exp: 9/30/2024

Date of Self Assessment Form: 6/20/2021 Other Permit #: N/A Date of DEA Inventory: ___

Hours M-F: 8am-6pm Hours Saturday CLOSED Hours Sunday: CLOSED

PIC ERIK M CLAUSEN RPH60873 Administrator ___

RPH Consultant ___

| Staff | RPH Name: | License #: |
|---|---|---|
| | REBECCA M LEE | RPH75586 |
| | STEPHEN A CRAWFORD | RPH72636 |
| | TRUMAN H CHEUNG | INT44934 |
| | ALAN P CHAN | RPH59202 |
| | TRISHA R PETTICREW | RPH77807 |
| | REBECCA E WILD | RPH73324 |
| | MARJORIE ANNE G CHENG | RPH75020 |

| Staff Name: | License #: |
|---|---|
| AMANDA L SUMMERFIELD | TCH122031 |
| ARVIN A DULZURA | TCH140488 |
| HALEY J BAXLEY | TCH182341 |
| JANINE C GERMAN | TCH130852 |
| KAELEEN T BAJET | TCH173845 |
| KRISTINE G CHAW | TCH167296 |
| MELISSA V CASTILLO | TCH180282 |
| NATHANIEL A GABRIEL | TCH184904 |
| QUANISHA M SMITH | TCH156346 |
| RUBEN B BAUTISTA JR | TCH121980 |

**Inspector Remarks:**

Community Veterinary Compounding Pharmacy, warehouse
Compounding: yes, approximately 200 per day
Deliveries: yes, UPS, USPS, notice to consumer of their right to consultation, phone number and hours of operation prints out with each delivery and is placed in the delivery container.
Licensed in 49 other states

**Routine Inspection, COVID-19:**
**Pharmacist-in-Charge Erik Clausen, present during inspection**

Remarks:
Security
Hot and cold running water: yes
Notice to consumer Poster, posted in view of the public: yes

1 NA

**California State Board of Pharmacy**
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Language translation poster posted in view of the public: yes
PHY License posted in public view: yes
Offsite storage waiver, yes, #228648 and # 227647
Refrigerators/freezers and room temperature electronically monitored by: Traceable, alerts are sent via email and text.
Power of Attorney: yes
Biennial Inventory: 12/30/2022
CII reconciliation report: last on: 12/30/2022 (performed audit from June to December, they are aware it is a quarterely requirement).
Controlled substances perpetual inventory
Quality Assurance Report: last from 12/20/2022.
Community Pharmacy self-assessment: 6/20/2021
Compounding self-assessment: 6/20/2021
C2 and C3-5 Invoices, filed separately and signed by a Pharmacist
Wholesaler: Medisca, Fagron, Letco, PCCA, MWI (division of Amerisource Bergen), Cardinal Health
Reverse Distributor: Pharmalogistics
Waste: Barnett Medical
Prescription label is patient centered
Opioid warning label: warning of risk of overdose or addiction on controlled substance prescripiton, it prints out on the prescription label.
DEA 106: None
CSOS: used for ordering CII controlled substances.
References: IJPC, Compounding Today, PCCA, Trissels, Plums
Reviewed dispensed controlled substance paper prescriptions, CII and CIII-CV
Policies and Procedures: job descriptions, Non-sterile Compounding, temporary absence of a pharmacist, language translation services and theft/impairment, recalls, performance improvement, quality assurance program, employee training, Cytotoxic or hazardous drug spills, garb,

Compounding:
Description of modular compounding area: anteroom leads to hazardous compounding room with 2 exhausted BSC IV Hoods, and two non-hazardous compounding rooms. One NH compoudnig room has six powder hood and a pass through, and the other NH compounding room has two powder hoods.
Batch compounding of non-sterile compounded drug products. controlled substances, hazardous (NIOSH Table 1-3) and non-hazardous compounding.
Hoods: certified by ENV Services anually, last on 8/23/2022. All ten hoods passed.
Master Formulas: reviewed methimazole 5mg/ml suspension, methimazole 2.5mg/0.1ml transdermal pen, Maropitant 10mg/ml suspension, Ursodiol 90mg capsule
Compounding records: reviewed lot #520019, for: Methimazole 5mg/ml suspension, Lot #538757, Methimazole 2.5mg/0.1ml transdermal pen, Lot#539859, Maropitant 10mg/ml suspension, Lot 539469, Ursodiol 90mg capsule.
Prescription label reviewed: The type appears smaller than 12-point Sans Serif typeface, please check with Pharmedika, CCR 1707.5 (a)(1). There are no storage instructions as required by CCR 1735.4(a)(3) and the date compounded is not listed as required by CCR 1735.4(a)(5).
Quality Assurance testing: 8/12/2022 gabapentin 100mg/ml, 94.9% potency.
On-going competency evaluation: TCH Melissa Castillo and RPH Alan Chan. Hazardous chemical acknowledgement. Competency evaluation in the past year, includes potency test of compounded drug.
Cleaning records: Pestle software.
Cleaning agents: 70% IPA, Saniwipes, Clorox wipes, Hydrogen Peroxide

**California State Board of Pharmacy**
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Pressure, temperature and humidity records: reviewed
Annual review of compounding policies and procedures by the PIC, last on and around 9/2021. PIC aware it has been over a year. The policies and procedures are currently in review.
Eye wash stations

**Discussion/Education:**
1) **California Code of Regulations Section 1732.5 – Pharmacist Renewal Requirement:** Pharmacist are required to complete 2 of the 30 hours of Continuing Education in the prior 24 months to renew their pharmacist license by participation in a Board provided CE course in Law and Ethics. The two hours of continuing education are currently posted on the board's website at www.pharmacy.ca.gov. Pharmacist renewing their licenses which expires on or after July 1, 2019 are subject to this requirement. Print certificate of completion after online course is completed and maintain for four years.Available on Board's website: http://www.pharmacy.ca.gov/licensees/webinars/law_ethics.shtml.
2) Recommend reviewing USP 795, which becomes official and enforceable on 11/1/2023.
3) Recommend not compounding hazardous compounded drug products until the hazardous compounding room has been certified to have at least 12 air changes per hour and maintain negative pressure in the range of (-0.01-0.03" water column). On top of modular room the fan motor has a red light today. Fan or motor may have stopped working today. The pressure was last checked at 930am today and was -0.03" water column.
4) Recommend labeling the compounded drug quarantine area (currently red "on-hold labels placed on quarantined compounded drugs which are placed in an area away from active inventory, a green label is then placed on the compounded drugs over the red label when they are approved and released for use).
5) Recommend revising cleaning document for area where pharmacists work, it states they are cleaning compounding work surfaces.
6) Recommend revising SOP 6.004 for non-sterile compounding finished preparation testing, as it states all compounded products shall be quarantined until documentaiton of results of release testing and inspections are complete which is not the current practice.

**Corrections/Violations:**
1) CCR 1735.4(a)(3): There are no storage instructions on the compounded drug prescription label.
2) CCR 1735.4(a)(5): The date compounded is not listed on the compounded drug prescription label.
3) CCR 1735.6(e)(1): Hazardous non-sterile compounding room does not have the number of air changes per hour documented by a certification company.
4) CCR 1735.63(e)(2): Hazardous non-sterile compounding room had positive pressure on the ENV cerification report from 4/7/2022 (0.0343" water column), instead of negative pressure. During the inspection, the room had positive pressure noted by PIC and Inspector by feeling airflow on hands coming out of the vent in the door to the room and the magnahelic gauge read 0.01" positive pressure. However, the print out of the electronic pressure was -0.03 " water column today at 9:34.
5) CCR 1735.3(a)(2)(F): The compounding records reviewed showed the manufacturer does not always print out under the ingredients used in compounding the drug product. For ingredients compounded in house, please be sure they state (compounded in house or similar).
6) BPC 4076.7: Opioids are dispensed without a warning of risk of overdose and addiction.

"Pursuant to Business and Professions Code 4083, a licensee of the California State Board of Pharmacy, may submit a written request within 30 days of service of the order of corrections, for an office conference with the board's executive officer to contest the order of correction."

Please send the action item(s) and remedial actions for the corrections/violations with 14 days, by close of business

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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
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on **2/16/2023.**

Denise Dukatz, Pharm D.
Inspector
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: 415-629-9319
Fax: 415-242-6219
Email: denise.dukatz@dca.ca.gov

**Licensee Remarks:**

I have reviewed, discussed,understand and received a copy of this form.

Pharmacist (sign) _____

Pharmacist (print) Erik Clausen

Inspector (sign) _____

Inspector (print) Denise Dukatz

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

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# ORDER OF CORRECTION

Date: 2/2/2023 Permit #: PHY58192

Time of Day: 12:58 PM

Name as shown on permit: **BRAVA CA LLC**

Address: 8 DIGITAL DR STE 104 City: NOVATO

Please be advised it appears there is a failure to comply with the following laws governing the practice of pharmacy, and/or the rules and regulations of the Board of Pharmacy:

| | |
|---|---|
| 1. **CCR 1735.3(a)(2)(** | Recordkeeping for Compounded Drug Preparations . For each compounded drug preparation, the pharmacy records shall include: A compounding log consisting of a single document containing all of the following: The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply.<br>In that, at the time of inspection, lot 538757, Methimazole 2.5mg/0.1 transdermal pen did not list a manufacturer for the methimazole on the compounding record. In addition, lot 520019, for methimazole 5mg/ml suspension, did not list the manufacturer for anhydrous suspending vehicle (compounded in house), lot 539859, for maropitant 10mg/ml suspension did not list the manufacgturer for anhydrous suspensing vehicle. |
| 2. **CCR 1735.4(a)(5)** | Labeling of Compounded Drug Preparations. Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least: The date compounded; and<br>In that, at the time of inspection, rx: 616014, for compounded drug: Pimobendan 5mg capsules does not list the date compounded. |
| 3. **CCR 1735.4(a)(3)** | Labeling of Compounded Drug Preparations. Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least: Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;<br>In that, at the time of inspection, rx: 616014, for compounded drug: Pimobendan 5mg capsules did not list storage instructions. |

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| | |
|---|---|
| 4. CCR 1735.6(e)(1) | Compounding Facilities and Equipment. Hazardous drug compounding shall be completed in an externally vented exhausted physically separate room with the following requirements: Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hours or less or when non sterile products are compounded; and<br><br>In that, at the time of inspection, the hazardous compounding for non-sterile products area does not have the number of air changes per hour documented on the certification reports. Please have the number of air changes per hours checked and send a copy to the Inspector. |
| 5. CCR 1735.6(e)(2) | Compounding Facilities and Equipment. Hazardous drug compounding shall be completed in an externally vented exhausted physically separate room with the following requirements: Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and<br><br>In that, at the time of inspection, the hazardous compounding for non-sterile products area does not have negative pressure of 0.01 to 0.03 inches of water column relative to all adfacent spaces. The room has positive pressure 0.01 " water column relative to all adjacent spaces today per the magnahelic gauge. ENV services documents positive pressure of 0.363 on 4/7/2022. Please get the air pressure direction fixed and send certification report to Inspector showing the room has negative pressure with the correct pressure range. |
| 6. BPC 4076.7 | Caution Label Required for Drug Containing an Opioid. In addition to the requirements of Sections 4076 and 4076.5, whenever a prescription drug containing an opioid is dispensed to a patient for outpatient use, the pharmacy or practitioner dispensing the drug shall prominently display on the label or container, by means of a flag or other notification mechanism attached to the container, a notice that states "Caution: Opioid. Risk of overdose and addiction."<br><br>In that, at the time of inspection, the pharmacy dispenses opioids for animals and does not have the opioid caution auxiliary sticker stating there is a risk of over dose and addiction. |

*I have reviewed, discussed, understand and received a copy of this form.*

Inspector (sign) _____

Inspector (print) Dennis Dobbs

Date 2/2/2023

Signed _____

Print Name Erik Clausen

Title General Manager + PIC

Pursuant to Business and Professions Code §4083, a licensee of the California State Board of Pharmacy, may submit a written request within 30 days of service of the order of correction, for an office conference with the board's executive officer to contest the order of correction.

Erik Clausen <erik.clausen@bravacare.com>

To: Nasro Ali <nasro.ali@bluerabbit.vet>

See below for correspondence with the BOP to resolve the corrections.

**Erik Clausen, PharmD/MBA**
General Manager & Corporate Pharmacist-In-Charge

phone: **(415) 455-5590**
email: **erik.clausen@bravacare.com**
website: **bravacare.com**

a




We're excited to introduce our new name! More updates are coming soon as we build an even better experience for veterinarians, clients, and the pets we all love.

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---

**From:** Dukatz, Denise@DCA <Denise.Dukatz@dca.ca.gov>
**Sent:** Wednesday, February 15, 2023 8:34 AM
**To:** Erik Clausen <erik.clausen@bravacare.com>
**Subject:** RE: Corrections

Dear Erik Clausen,

Thank you for sending the remedial actions for the corrections issued during an inspection on 2/2/2023. They have been received and accepted. This concludes this inspection.

Kind Regards,

Denise Dukatz



California State Board of Pharmacy
(415)629-9319 | FAX (415)242-6219 | **denise.dukatz@dca.ca.gov**

WARNING:

erik.clausen@bravacare.com

Hi Denise,

Please find attached the following documents:

1. CCR 1735.3(a) - a sample worksheet for Methimazole showing manufacturer information for the methimazole lot in question. We identified that the lot number for the methimazole that was missing from the manufacturer was due to that lot number coming over incorrectly during the data transition from our old software to the new software. We re-added the lot number under the correct manufacturer so it will be accurate moving forward. For our anhydrous suspension base, we added "manf in house" to the title to meet the requirement. See the attached master formula. We have not yet used a new batch, so it is still printing without the manufacturer, but all future batches should indicate that in the title. In the meantime, we are putting it in the notes (see methimazole sample formula). We also notified staff that if they see a similar situation moving forward with any other products, to a) notify management so we can rectify and b) notate the manufacturer in the notes until the problem is resolved.
2. CCR 1735.4(a)(5) - a sample label showing the "date compounded" on the label. This was actually something that the software was doing, but the date compounded was cut off on the sample label provided to you that day.
3. CCR 1735.4(a)(3) - a sample label showing the room temperature storage requirement added to the label. All room temperature formulations are currently being updated to reflect this requirement.
4. CCR 1735.6(e)(1) - an updated certification report showing negative pressure and air changes per hour in the USP 800 Hazardous Lab
5. CCR 1735.6(e)(2) - an updated certification report showing negative pressure and air changes per hour in the USP 800 Hazardous Lab as well as previous documentation showing that the HVAC units were being serviced at the time of the inspection resulting in the positive pressure at that time.
6. BPC 4076.7 - A sample of the opioid auxiliary label in use since the inspection

Please let me know if there is anything else that you should need from me. Thank you very much for your time and guidance.

Regards,

Erik Clausen

**Erik Clausen, PharmD/MBA**
General Manager & Corporate Pharmacist-In-Charge

phone: **(415) 455-5590**
email: **erik.clausen@bravacare.com**
website: **bravacare.com**

We're excited to introduce our new name! More updates are coming soon as we build an even better experience for veterinarians, clients, and the pets we all love.

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# Methimazole 25mg/ml Suspension [ 27621]

Date compounded: 2023-02-14 14:56

Lot #: 550181

15c11764-a631-4c06-9648-977718927451

Formula Type: Anhydrous Suspension
Estimated Time:
Location: Not Set
Formula stability span: 180 days
Hazardous
Quantity: 32
Beyond Use: 2023-08-01
Task Performed By: Janine German, Brenda Luke
Verified By: Brenda Luke
Station:
Preparation Environment: Specific Pressure Environment Not Required/Not Used
Route of Administration: Oral route

**Ingredients**

METHIMAZOLE USP 53843 — **0.800gm** — Checked By: Brenda Luke [2023-02-14 3:29:13 pm]

**Lots:**
2203160080 [LETCO MEDICAL - 62991151505]
Beyond Use: 2023-11-16
Quantity Used: 0.799

**Measurements Log**
0 [ jgerman - 2023-02-14 2:58:24 pm]
~~0.798~~ [ jgerman - 2023-02-14 3:00:04 pm]
0.799 [ jgerman - 2023-02-14 3:00:11 pm]
0 [ jgerman - 2023-02-14 3:00:26 pm]

Anhydrous Suspending Vehicle 53491 — **QS to 32.000mL** — Checked By: Brenda Luke [2023-02-14 3:29:14 pm]

**Lots:**
542438
Beyond Use: 2023-08-01
Quantity Used: 32.000

**Measurements Log**
32 [ jgerman - 2023-02-14 3:00:33 pm]

VETERINARY FLAVORING (OIL) 12391 — **0.320 / 0.320mL**

**Lots:**
2208040192 [LETCO MEDICAL - 62991315902]
Beyond Use: 2023-09-28
Quantity Used: 0.320

**Measurements Log**
0.32 [ jgerman - 2023-02-14 3:00:56 pm]

Total Weight: 0.799

**Equipment Used:**

| Equipment Name | User |
|---|---|
| Scale Quintix 09 | jgerman 2023-02-14 2:57 pm |

**Instructions**

EQUIPMENT NEEDED: POWDER CONTAINMENT HOOD, ANALYTICAL BALANCE, WEIGH BOATS, SPATULAS FOR WEIGHING, MORTAR AND PESTLE OR OTHER SUITABLE MIXING DEVICE, SYRINGE OR OTHER SUITABLE MEASURING DEVICE FOR LIQUIDS, AMBER VIAL FOR DISPENSING

1. WEIGH OUT POWDER INGREDIENTS AND RECORD WEIGHT
If using tablets, place the appropriate number of tablets in a mortar, pulverize, then triturate to a fine, uniform powder. If using capsules, open each capsule and empty entire contents into mortar. Then triturate to a fine, uniform powder. If using commercial solution, measure out appropriate amount.
2. WET POWDER (OR MIX LIQUID INGREDIENTS) WITH ANHYDROUS SUSPENDING VEHICLE AND MIX INTO A

SMOOTH PASTE, THEN QS TO FINAL VOLUME WITH REMAINING ANHYDROUS SUSPENDING VEHICLE AND MIX WELL TO ENSURE ALL INGREDIENTS ARE INCORPORATED. MIXING TIME: ~1-2 MINUTES.
3. ADD OIL MISCIBLE FLAVOR AND MIX WELL TO INCORPORATE FLAVOR. MIXING TIME: ~1-2 MINUTES
4. SHAKE WELL, DISPENSE IN AN AMBER VIAL, STORE AT ROOM TEMPERATURE

Tasks

☑ Record Weight of Active Ingredients [ Janine German]

☐ Record Weights of Inactive Ingredients if Applicable [ ⚠Incomplete]

☑ Document Volume of Liquid Ingredients [ Janine German]

Documents

☑ Description of Final Product with Photo [ Janine German]

Documents

**Category:**

| Name | Note Preview |
|---|---|
| |  |

**Final Appearance: MILKY WHITE/CLOUDY SUSPENSION. FLAVORING MAY DARKEN AND ADD DISTINCTIVE SCENT.**
**Packaging: USP GRADE, TIGHT, WELL-CLOSED, LIGHT RESISTANT CONTAINER**
**Storage Instructions: ROOM TEMPERATURE**

**Packaging:**
USP GRADE, TIGHT, WELL-CLOSED, LIGHT RESISTANT CONTAINER

**Storage Instructions:**
ROOM TEMPERATURE

**Final Appearance:**
MILKY WHITE/CLOUDY SUSPENSION. FLAVORING MAY DARKEN AND ADD DISTINCTIVE SCENT.

**Final Yield: 30 mL**

**Containers:** 1

**Note:** Anydrous Base Manf In House

# Anhydrous Suspending Vehicle (Manf: Brava CA LLC) [53491] active

Formula Name
Anhydrous Suspending Vehicle (Manf: Brava CA LLC)
Formula ID
53491
NDC
99000854972

☑ Add as ingredient?
Formula Type
Special Instruction Formula
Dosage Form
Suspension
Route of Administration
Oral route

☐ Sterile

Therapy Class
Other

Task Points
0
Required Time
Location
Stability Span
180
Status: active
Verified: 2023-02-09 by Erik Clausen [2]
Last Modified: 2023-02-09 by Erik Clausen

**Auxiliary Labels**

Shake Well

**Ingredients**

| Description | Require Measurement Check<br>Quantity Sufficient | Quantity |
|---|---|---|
| MCT OIL<br>Code: 53779 | ☑ Check<br>☐ QS | 40 mL |
| GLYCERYL MONOSTEARATE<br>Code: 53672 | ☑ Check<br>☐ QS | 1.1 gm |
| STEVIA EXTRACT 90%<br>Code: 52878 | ☑ Check<br>☐ QS | 0.08 gm |

Total Weight

**Quantity:** 40

**Instructions**

Tasks

- WEIGH OUT GLYCERYL MONOSTERATE AND STEVIA AND RECORD WEIGHTS
- INCLUDE DOCUMENTATION OF LIQUID INGREDIENT VOLUME
- DESCRIPTION OF FINAL PRODUCT

› **Details**
Stability Supporting Documentation

USP 795 FOR NON-AQUEOUS LIQUID PREPARATIONS

Chemical Compatibility

Packaging

Storage Instructions

STORE AT ROOM TEMPERATURE

Final Appearance

MILKY WHITE/CLOUDY

SOP/Reference Documentation

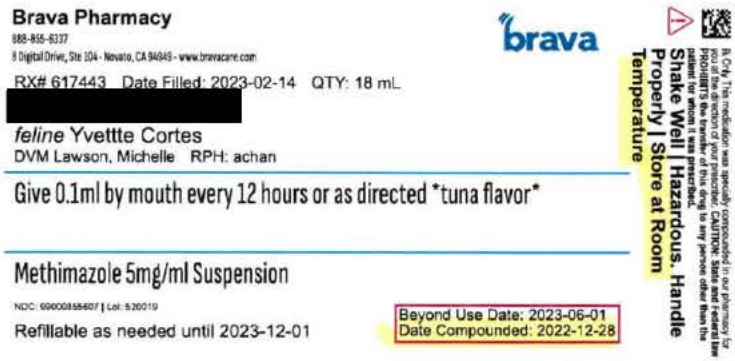
Documents

**Anticipatory Compounding Limit:** N/A - Download




**History**

| Date | User | Note |
|---|---|---|
| 2022-09-08 4 pm | ElectricLab | conversion |
| 2022-09-24 9 pm | Vigil Rapiz | not all caps now |
| 2023-02-09 5 pm | Erik Clausen | update name |
| 2023-02-09 5 pm | Erik Clausen [2] | Formula re-activated |



**Brava Pharmacy**
888-855-8337
8 Digital Drive, Ste 104 - Novato, CA 94949 - www.bravacare.com

RX# 617443 Date Filled: 2023-02-14 QTY: 18 mL

[redacted]

*feline* Yvettte Cortes
DVM Lawson, Michelle RPH: achan

Give 0.1ml by mouth every 12 hours or as directed *tuna flavor*

Methimazole 5mg/ml Suspension

NDC: 69000855607 | Lot: 520019

Refillable as needed until 2023-12-01

Beyond Use Date: 2023-06-01
Date Compounded: 2022-12-28

Shake Well | Hazardous. Handle Properly | Store at Room Temperature

R Only This medication was specially compounded in our pharmacy for the patient named above and is not to be used by any other person. FEDERAL LAW PROHIBITS the transfer of this drug to any person other than the patient for whom it was prescribed.

2880 Bergey Road, Ste. K
Hatfield, PA 19440
www.envservices.com
800 - 345 - 6094

*Presents:*

# Certification Report

## Control ID #: 6008-294292-49779

*Prepared for:*

GOLDEN GATE VETERINARY
8 DIGITAL DRIVE, SUITE 104
NOVATO, CA 94949

*Location Tested:*

NEGATIVE PRESSURE RM

*Date(s) Tested:*

**07 FEB 2023**

*Field Service Technician(s):*

**SHAWN DONALDSON**

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# SUMMARY REPORT

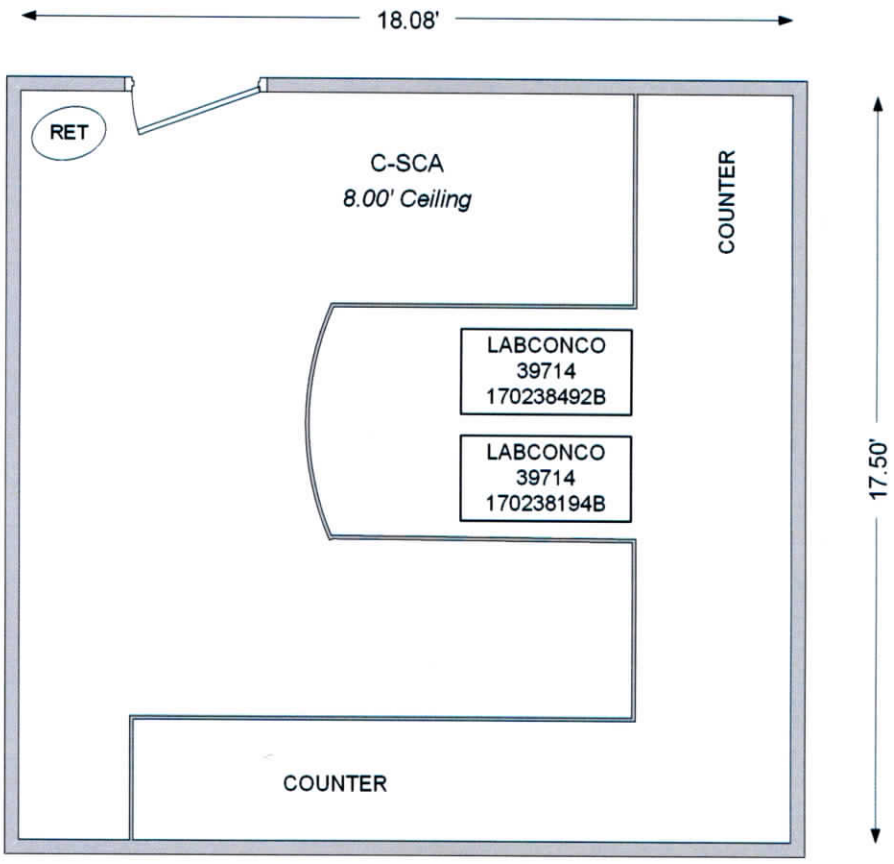
NEGATIVE PRESSURE RM
GOLDEN GATE VETERINARY
NOVATO, CA 94949

*All testing is performed by qualified personnel using instrumentation, procedures, and methods which ensure measurements observed are reliable. All Testing is performed in accordance with current versions of ISO-17025, ISO-14644, USP<797>, <USP800>, <USP825>, and ENV's Quality Manual. Specifications comply with applicable IEST recommended practices, Current versions of CETA CAG-003-2006-13 for Sterile Compounding Facilities, CETA CAG-009 Viable Environmental Monitoring for Sterile Compounding Facilities, and/or customer determined specifications when applicable. Measurement instruments used are traceable to The National Institute of Standards and Technology (NIST). Results obtained apply to the specific room or equipment and are reflective of conditions at the time of this test.*

| ROOM PRESSURIZATION | | | | |
|---|---|---|---|---|
| **Test** | **Test Result** | **Specification** | **Pass / Fail** | **Comment** |
| **C-SCA TO AMBIENT:** | Negative \| 0.028 | Negative \| 0.010 - 0.030 | PASS | |
| **C-SCA** | | | | |
| **Test** | **Test Result** | **Specification** | **Pass / Fail** | **Comment** |
| **Total Air Changes / Hr.** | 20 | ≥ 12 | PASS | |

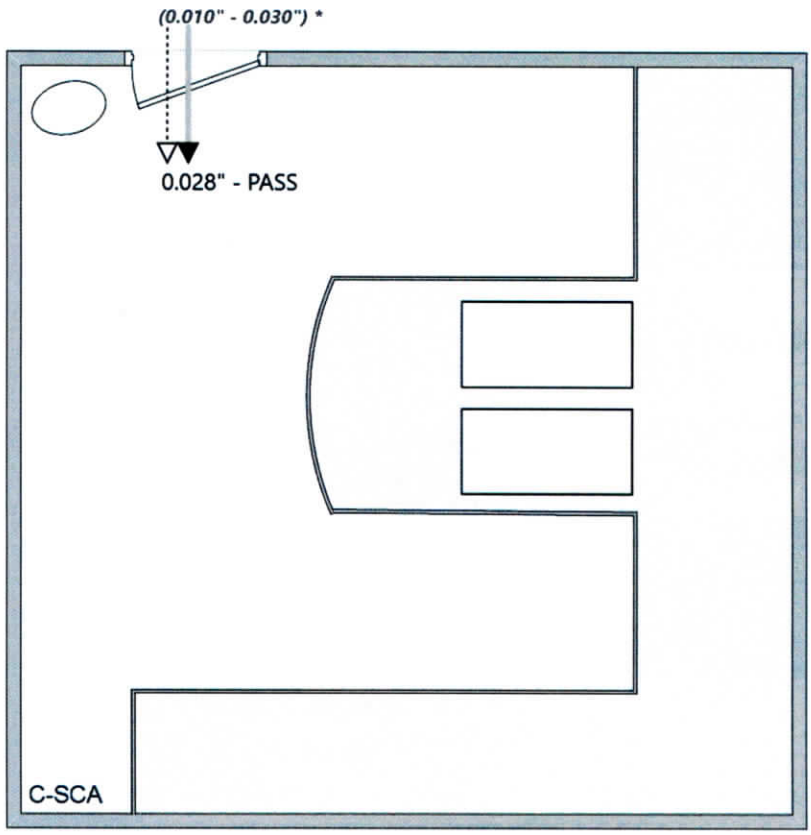
# OVERVIEW

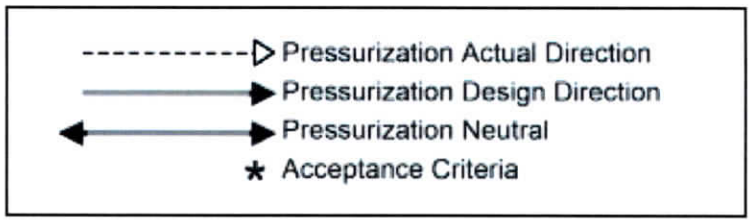
NEGATIVE PRESSURE RM
GOLDEN GATE VETERINARY
NOVATO, CA 94949



# ROOM PRESSURIZATION

NEGATIVE PRESSURE RM
(UNITS IN INCHES WATER GAUGE) - OPERATIONAL / DYNAMIC
ROOM PRESSURIZATION

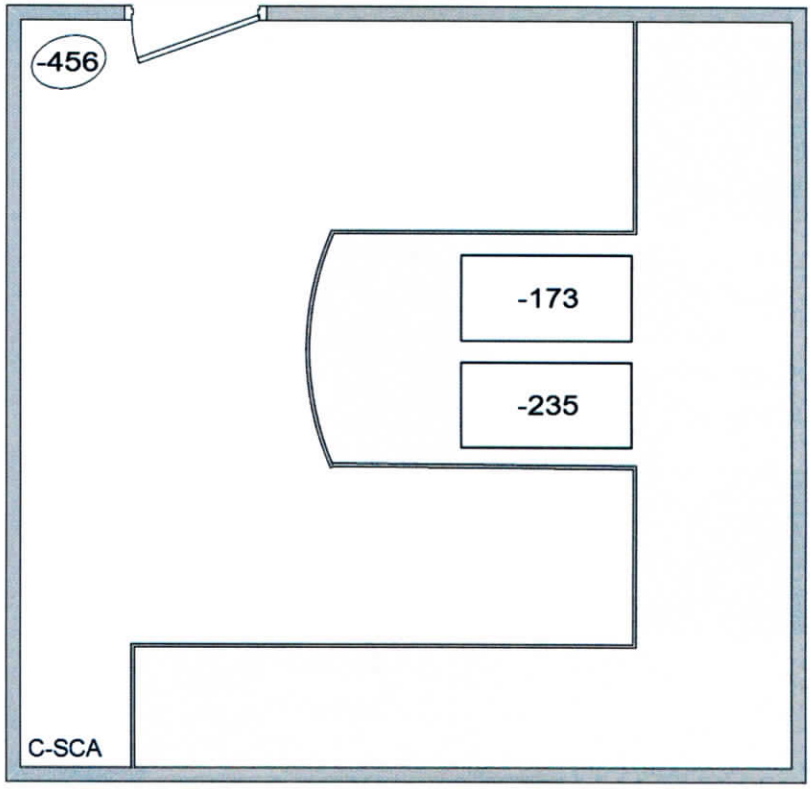



**Test Result**
PASS

# AIR EXHAUST VOLUMES & AIR CHANGES PER HOUR

NEGATIVE PRESSURE RM
(UNITS IN CUBIC FEET PER MINUTE) - OPERATIONAL / DYNAMIC
C-SCA




| | |
|---|---|
| 2531 | Room Volume |
| 3 | No. of Readings |
| 864 | Total Air Exhaust Volume |
| 20 | Room Air Changes/Hour |
| 12 | Room ACH Specification |

**Test Result**
PASS

# TEST EQUIPMENT

NEGATIVE PRESSURE RM
GOLDEN GATE VETERINARY
NOVATO, CA 94949

| Equipment Name | Manufacturer | Model | Serial | Calibration Due Date |
|---|---|---|---|---|
| ELECT. BALANCING TOOL | ALNOR | EBT721 | 90810046 | 30 JUN 23 |

**Test equipment calibration certificates available upon request.**
**Company ID: CA0156-001 Unique ID: 621522**



Renewal Certificate

# Retail Pharmacy Permit

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

VOID VOID VOID

# BOARD OF PHARMACY

## LICENSING DETAILS FOR: PHY 58192

**NAME:** BRAVA CA LLC

**LICENSE TYPE:** PHARMACY (COMMUNITY)

**LICENSE STATUS:** CLEAR

**ADDRESS**

8 DIGITAL DR STE 104
NOVATO CA 94949
MARIN COUNTY

**ISSUANCE DATE**

MAY 24, 2021

**EXPIRATION DATE**

MAY 1, 2024

**CURRENT DATE / TIME**

JUNE 5, 2023
9:56:59 AM

## LICENSE RELATIONSHIPS

**NAME:** CLAUSEN, ERIK MATTHEW

**ADDRESS NOT DISCLOSED**

**LICENSE/REGISTRATION TYPE:** REGISTERED PHARMACIST

**LICENSE NUMBER:** 60873 **PRIMARY STATUS:** CLEAR

**California State Board of Pharmacy**
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

May 16, 2023

## California State Board of Pharmacy License Verification

This document reflects the license status of the person or entity identified below on this date with the California State Board of Pharmacy. It may be used as prima facie evidence of the facts recited below pursuant to California Business and Professions Code section 162.

**Licensee Name:** BRAVA CA LLC

**License Type:** PHARMACY

**License Number:** PHY 58192

**Status:** ACTIVE

**Issue Date:** 05/24/2021

**Expiration Date:** 05/01/2024

**Address of Record:** 8 DIGITAL DR STE 104 NOVATO, CA 94949

**Disciplinary Action:** NO RECORD OF DISCIPLINARY ACTION

Anne Sodergren
Executive Officer

By Ann Altamirano

Ann Altamirano
Public Inquiry Analyst
(916) 518-3045
Pharmacy.PublicRecords@dca.ca.gov

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| FG0344767 | 07-31-2024 | $888 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N,3, 3N,4,5 | RETAIL PHARMACY | 06-02-2021 |

BRAVA CA LLC
8 DIGITAL DR STE 104
NOVATO, CA 949495759

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

**THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.**

**CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE**
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| FG0344767 | 07-31-2024 | $888 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N,3, 3N,4,5 | RETAIL PHARMACY | 06-02-2021 |

BRAVA CA LLC
8 DIGITAL DR STE 104
NOVATO, CA 949495759

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

ReedSmith
Driving progress
through partnership

**Kelly J. Kearney**
Direct Phone: +1 415 659 4756
Email: kkearney@reedsmith.com

Reed Smith LLP
101 Second Street
Suite 1800
San Francisco, CA 94105-3659
+1 415 543 8700
Fax +1 415 391 8269
reedsmith.com

**June 6, 2023**

**Via UPS**

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway Suite 206
Reno, NV 89521

**Re: Brava CA LLC (Nevada License No. PH04110)**

Dear Nevada Board of Pharmacy:

On behalf of the applicant Brava CA LLC ("Brava CA"), please accept the enclosed Pharmacy Application and accompanying forms and attachments for review and approval. Also enclosed is a check made out to Nevada State Board of Pharmacy in the amount of $500.00.

By way of background, Brava CA is a veterinary compounding pharmacy located in Novato, California. On or about **June 13, 2023**, Brava CA will undergo a **change of ownership at the great-great grandparent level**. On or about that date, Specialty Pharma I, Inc. will purchase all of the issued and outstanding common shares of Blue Rabbit Ventures Inc., the great grandparent owner of Brava CA. Accordingly, post-closing, Specialty Pharma I, Inc. will be the new great-great grandparent owner of Brava CA.

As a result of this change of ownership, Brava CA will obtain a new home state permit from the California Board of Pharmacy. There will be **no change** to Brava CA's name, location, FEIN, corporate status as a limited liability company, and day-to-day management and operations post-closing. For ease of reference, we have enclosed before and after organization structure charts demonstrating the nature of the change, as well as updated ownership information.

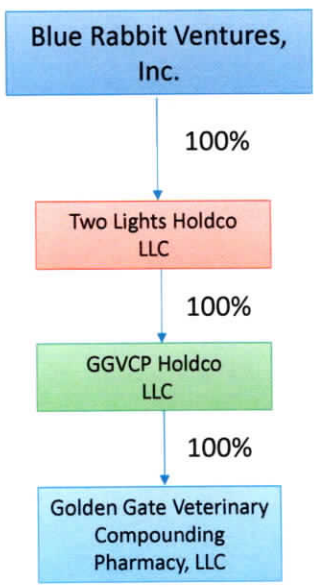
Should you require any additional information during the application review process, please contact me at 415-659-4756 and kkearney@reedsmith.com, or my colleagues Amica Nesbitt at 312-207-2777 and anesbitt@reedsmith.com and Madhav Bhatt at 312-207-2903 and mbhatt@reedsmith.com.

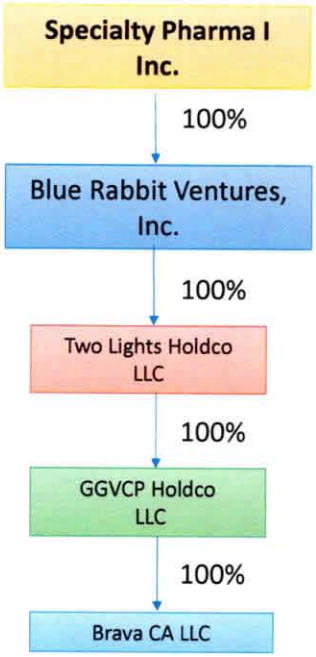
Very truly yours,

*Kelly J. Kearney*

Kelly J. Kearney
For Reed Smith LLP

Pre-Close Organizational Structure






← New great-great grandparent.

Post-Close Organizational Structure

This portion of the corporate structure is remaining the **same** post-closing

# Brava CA LLC
## Officers and Parent Company

**Brava CA LLC Officers:**

Erik Clausen, President
8 Digital Drive, Suite 104
Novato, CA 94949

Home Address: [redacted]ander Place, Novato, CA 94945

Joel Heberlein, CFO/Treasurer
2 Union Street, Suite 500
Portland, ME 04101

Home Address: [redacted]Damon's Place Circle, Marshfield, MA 02050

Ann Randall, Secretary
2 Union Street, Suite 500
Portland, ME 04101

Home Address: [redacted]lberta Way, Gorham, ME 04038

**Brava CA LLC Parent Company:**

GGVCP Holdco LLC
2 Union Street, Suite 500
Portland, ME. 04101

Officers: Benjamin Shaw, President
2 Union Street, Suite 500
Portland, ME 04101

Home Address: 6 Sunny Bank Road, Cape Elizabeth, ME 04107

# 4MM

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Pharmacy Application

**Non-Refundable $500.00 Fee**

Rev (9/22/2021)

**Where is the facility located?**

- ☐ Nevada
- ■ Out-of-State

| Type of Application (check applicable box) | | Ownership Type (check applicable box) |
|---|---|---|
| ☐ New Pharmacy<br>■ Ownership Change*<br>☐ Location Change *<br>■ Name Change* | * If making a change, provide current license number:<br>PH 02828 | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)<br>■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)<br>☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)<br>☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12) |

### Section 1: General Information

Pharmacy Name: KINGS PARK SLOPE LLC

Physical Address: 357 FLATBUSH AVE

City: BROOKLYN State: NY Zip: 11238

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 718-230-3535 Toll Free # (NAC 639.708, NRS 639.23286): 800-795-4647

Fax: 718-230-0596 Contact Email: INFO@KINGSRX.COM

Website: WWW.KINGSRX.COM

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): NY: DMITRY VAGMAN / NV: MARTA GIAMMARINO

Supervising/Managing Pharmacist NV Pharmacist Registration #: 22796

**Type of Pharmacy (check all applicable)**

- ■ Retail/Community
- ☐ Hospital (# beds _____)
- ☐ Internet
- ☐ Nuclear
- ☐ Other: _____

**Services the Pharmacy will Provide (check all applicable)**

- ■ Retail/Community
- ■ Non-sterile Compounding
- ☐ Sterile Compounding
- ☐ Mail-Order Service
- ☐ Off-site Cognitive Services
- ☐ Long Term Care
- ☐ Hospital
- ☐ Other:

**Days of Operation**

■ Monday ■ Tuesday ■ Wednesday ■ Thursday ■ Friday ■ Saturday ■ Sunday

**Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)**

| | |
|---|---|
| Name: Marta Giammarino | NV Pharmacist Registration #: 22796 |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |

| **Section 3: History of Company** | **Yes** | **No** |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✔ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction? | | ✔ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry? | | ✔ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✔ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✔ |

**If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.**

**Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)**

| | | |
|---|---|---|
| Name: N/A | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

**Section 5: Publicly Traded Corporation**

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 6: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: New York

Parent Company (if any): Prima Health Holdings, LLC

Corporation/Organization Name: Kings Park Slope, LLC

Mailing Address: 357 Flatbush Ave

City: Brooklyn State: NY Zip: 11238

Telephone: 718-230-3535 Email: info@kingsrx.com

Contact Person Name: Dmitry Vagman

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ■ No

**Section 7: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 8: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

| Section 12: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)** | ✓ | ✓ SEE ATTACHEMENT | | |
| • **List the top four stockholders and their percent ownership. NRS 639.231(3)** | ✓ | ✓ SEE ATTACHEMENT | | |
| • **List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)** | | ✓ SEE ATTACHEMENT | | |
| • **For General Partnerships, list the name of each partner. NAC 639.214(2)**<br>• **For Limited Partnerships, list the names of (NAC 639.214(3)):**<br>○ **All General Partners;**<br>○ **All Limited Partners who hold 10% or more of the interest.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** from the Secretary of State's Office where the business is domiciled, dated within the last **6 months**. | CURRENT CERTIFICATE ATTACHED. UPDATED CERTIFICATE OF GOOD STANDING TO BE PROVIDED WHEN LLC IS FORMED AS PART OF THE CHANGE OF OWNERSHIP TRANSACTION. | | | |
| • **Designated Representative form** must be completed by the Designated Representative. Form is found at http://bop.nv.gov/Services/newapps/Business/. NAC 639.5005. The requirement does not apply to:<br>a. An applicant or a licensee that is a publicly traded corporation;<br>b. An applicant or licensee whose pharmacy is determined by the Board to be located within a large retail store, including, without limitation, a grocery store, variety store or department store under common ownership; or<br>c. An applicant or licenses in which a majority interest of the applicant or licensee is owned by a pharmacist who is:<br>1) License by the Board; and<br>2) A resident of this state. | | ✓ | ✓ | ✓ |
| • **Personal History Record Application found at** http://bop.nv.gov/Services/newapps/Business/ must be completed by:<br>**a. For Non-publicly traded** - The top 4 shareholder/stockholders.<br>**b. For Partnerships** - All general partners; all limited partners who hold 10% or more of the interest.<br>**c. For Sole Owner** - The owner. | NOT APPLICABLE BECAUSE THE APPLICANT (KINGS PARK SLOPE, LLC) IS 100% DIRECTLY OWNED BY AN LLC, PRIMA HEALTH HOLDINGS, LLC. | ✓ | ✓ | ✓ |
| • **Submit a copy of your most recent pharmacy inspection** from the regulatory or licensing authority of the state, territory or Federal agency in which the pharmacy is located. **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2328(2)(f) | ✓ | ✓ | ✓ | ✓ |
| • **Submit a copy of your license, certification, permit or registration issued to your pharmacy** from the regulatory board or licensing authority of the state or territory in which the pharmacy is located. **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2328(2)(a) | CURRENT COPY PROVIDED, BUT IS SUBJECT TO CHANGE DUE TO RESIDENT STATE CHANGE OF OWNERSHIP APPLICATION; UPDATED VERSION WILL BE PROVIDED WHEN ISSUED | | | |
| • **License Verification** by the regulatory board or licensing authority of the state or territory in which the pharmacy is located. You may use the form here: https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/2020%20ALL_LicenseVerificationForm(1).pdf **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2238(2)(g) | SEE ATTACHED FOR VERIFICATION OF CURRENT LICENSE. UPDATED LICENSE VERIFICATION WILL BE PROVIDED WHEN NEW/UPDATED RESIDENT LICENSE IS ISSUED PURSUANT TO CHANGE OF OWNERSHIP APPLICATION | | | |
| • **Copy of DEA Registration if handling controlled substances (REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** | CURRENT COPY PROVIDED, BUT IS SUBJECT TO CHANGE DUE TO DEA CHANGE OF OWNERSHIP APPLICATION; UPDATED VERSION WILL BE PROVIDED WHEN ISSUED | | | |
| • **Internet Pharmacy Services Certification (REQUIRED FOR PHARMACIES PROVIDING INTERNET PHARMACY SERVICES)** | ✓ | ✓ | ✓ | ✓ |
| • **Transmit Controlled Substance Prescription Data-** Pharmacies dispensing scheduled II-V controlled substance for human consumption shall, not later than the end of the next business day after dispensing a controlled substance, upload to the Nevada Prescription Monitoring Program (PMP) the information described in paragraph (d) of subsection 1 of NRS 453.162. Registration information found at: https://bop.nv.gov/links/PMP/ | ✓ | ✓ | ✓ | ✓ |

**Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)**

**Statement of Responsibility**

1. I am the CEO (title) for KINGS PARK SLOPE LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

JAMES TEDORI

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

7/25/2023

Date

# Kings Park Slope, LLC
# Nevada Pharmacy Application – Ownership Change and Name Change
# ATTACHMENT

- **List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)**

| Kings Park Slope, LLC – Officers | |
|---|---|
| **Name** | **Officer Title** |
| James Tedori | CEO |
| Ronald Del Gaudio | President |

Kings Park Slope, LLC is a member-managed LLC and does not have any directors.

- **List the top four stockholders and their percent ownership. NRS 639.231(3)**

Kings Park Slope, LLC is directly owned 100% by Prima Health Holdings, LLC.

- **List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)**

Kings Park Slope, LLC is directly owned 100% by Prima Health Holdings, LLC.

**STATE OF NEW YORK**

**DEPARTMENT OF STATE**

**Certificate of Status**

I, ROBERT J. RODRIGUEZ, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

| | |
|---|---|
| **Entity Name:** | KINGS PARK SLOPE INC. |
| **DOS ID Number:** | 1107166 |
| **Entity Type:** | DOMESTIC BUSINESS CORPORATION |
| **Entity Status:** | EXISTING |
| **Date of Initial Filing with DOS:** | 08/25/1986 |
| **Statement Status:** | CURRENT |
| **Statement Due Date:** | 08/31/2022 |

I certify that the following is a list of documents on file in the Department of State for said entity:

| | |
|---|---|
| **Document Type:** | CERTIFICATE OF INCORPORATION |
| **Date of Filing:** | 08/25/1986 |
| **Entity Name:** | KINGS PARK SLOPE INC. |

| | |
|---|---|
| **Document Type:** | BIENNIAL STATEMENT |
| **Date of Filing:** | 04/15/1993 |
| **Effective Date:** | 08/01/1992 |

| | |
|---|---|
| **Document Type:** | BIENNIAL STATEMENT |
| **Date of Filing:** | 09/30/1993 |
| **Effective Date:** | 08/01/1993 |

| | |
|---|---|
| **Document Type:** | BIENNIAL STATEMENT |
| **Date of Filing:** | 08/01/1996 |

| | |
|---|---|
| **Document Type:** | BIENNIAL STATEMENT |
| **Date of Filing:** | 08/25/1998 |
| **Effective Date:** | 08/01/1998 |

| | |
|---|---|
| **Document Type:** | BIENNIAL STATEMENT |
| **Date of Filing:** | 08/14/2000 |
| **Effective Date:** | 08/01/2000 |

| | |
|---|---|
| **Document Type:** | BIENNIAL STATEMENT |
| **Date of Filing:** | 07/29/2002 |
| **Effective Date:** | 08/01/2002 |

| | |
|---|---|
| **Document Type:** | BIENNIAL STATEMENT |
| **Date of Filing:** | 09/09/2004 |
| **Effective Date:** | 08/01/2004 |

| | |
|---|---|
| **Document Type:** | BIENNIAL STATEMENT |
| **Date of Filing:** | 08/16/2006 |
| **Effective Date:** | 08/01/2006 |

| | |
|---|---|
| **Document Type:** | BIENNIAL STATEMENT |
| **Date of Filing:** | 04/06/2016 |
| **Effective Date:** | 08/01/2014 |

| | |
|---|---|
| **Document Type:** | BIENNIAL STATEMENT |
| **Date of Filing:** | 04/23/2021 |
| **Effective Date:** | 08/01/2020 |

Above space is left blank intentionally.

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on June 01, 2022 at 04:14 P.M.

ROBERT J. RODRIGUEZ, Secretary of State

Brendan C. Hughes

By Brendan C. Hughes
Executive Deputy Secretary of State

Authentication Number: 100001653934 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

THE UNIVERSITY OF THE STATE OF NEW YORK
THE STATE EDUCATION DEPARTMENT
OFFICE OF PROFESSIONAL DISCIPLINE

## PHARMACY INSPECTION REPORT ☐ Pharmacy ☐ M/W

Inspection # _____ conducted by

Investigator Roy Chan

Date 5/10/2018 Time In/Out 9:09 / 10:20

1. Routine
2. New Registration
3. Transfer Ownership
4. Discontinuance
5. Change of Name/Address
6. Medication Recall
7. Complaint Related
8. Follow-up to Previous Inspection
9. Special Project or Renovation

Reg. name King Park Style Inc

Trade name King Super Pharmacy

No. and Street 337 Eastern Ave

City Brooklyn County Kings Zip 11235

Reg. # 017279 Telephone 718-730-3[illegible]

Hours open per week 81 # RXs daily [illegible]

| Pharmacists' Names | Hrs. Per Week | License Number | License Date | License Displayed | Registration Displayed |
|---|---|---|---|---|---|
| S.P. Dmitry Vegman | 50 | 044853 | 7/14/97 | Y N | Y N |
| Pharm. Ronald Defendorf (Consultant) | 0 | 037991 | 2/15/[illegible] | Y N | Y N |
| Pharm. Tawanna Butler | 40 | 061933 | 7/17/[illegible] | Y N | Y N |
| Pharm. Grady Ivey | 50 | 046175 | 7/31/[illegible] | Y N | Y N |
| ~~Pharm.~~ Sharon Tadey | | | | Y N | Y N |
| Intern | | | | Y N | Y N |

Circle "S" if item is Satisfactory. Circle "N" if item is Not Satisfactory, and explain in Details of Inspection section below.
Be sure to include item number in explanation.

1. Registration name on exterior ..... S N
2. Licenses/current reg. displayed ..... S N
3. Registered pharmacist on duty ..... S N
4. Equip., facilities, and ref. items ..... S N
5. Price list available/current ..... S N
6. Drug stock current ..... S N
7. Stock properly branded ..... S N
8. Daily RX record ..... S N
9. Required RX filings ..... S N
10. DEA records complete/available ..... S N
11. Safety/approp. closures/containers ..... S N
12. RX labels required information ..... S N
13. Valid RX formats ..... S N
14. Substitution law compliance ..... S N
15. Required information on RXs ..... S N
16. Refill authorization/fill ..... S N
17. Refills in daily record ..... S N
18. Controlled substance compliance ..... S N
19. General sanitation ..... S N
20. Intern/unlicensed supervision ..... S N
21. Counseling offered/given/refusals documented ..... S N
22. Types of pharmacy (circle those applicable): retail, hospital, skilled nursing, assisted living, compounding, sterile preparation, internet, home delivery, mail delivery, nuclear, veterinary

**Details of Inspection** [illegible]

Recommendation (completed in office)

Investigator [signature]

Supervisor _____

I have received a copy of this inspection report.

Signature [signature]

Print name [illegible]

Title PIC Date [illegible]

This is page _____ of _____ page(s)

OPD 234 (6/2011) 11-005 CDC

ORIGINAL - TO CENTRAL OFFICE

THE UNIVERSITY OF THE STATE OF NEW YORK
THE STATE EDUCATION DEPARTMENT
OFFICE OF PROFESSIOMAL DISCIPLINE

## PHARMACY INSPECTION REPORT

Inspection # _____ conducted by
Investigator Ray Chan
Date 8/10/18 Time 9:09

Reg. name Kings Park Stage Inc
Trade name Kings Super Pharmacy

Details of Inspection

Recommendation (completed in office)

Investigator _____

Supervisor _____

I have received a copy of this inspection report.

Signature _____

Print name Meghan Butler

Title Pharmacist Date 8/10/18

ORIGINAL – TO CENTRAL OFFICE

This is page 2 of 2 pages

**RAY CHAN**
Senior Investigator
Office of Professional Discipline

New York State Education Department
9 Bond Street
Suite 4400
Brooklyn, New York 11201

Tel. (718) 722-2577
Fax (718) 722-2840
E-Mail: Lok.Chan@nysed.gov

NYSED.gov

OP Office of the Professions

## Office of the Professions

# Verification Searches

The information furnished at this web site is from the Office of Professions' official database and is updated daily, Monday through Friday. The Office of Professions considers this information to be a secure, primary source for license verification.

## Pharmacy Establishment Information *

06/14/2022

**Type :** PHARMACY
**Legal Name :** KINGS PARK SLOPE INC.
**Trade Name :** KINGS SUPER PHARMACY
**Street Address :**
357 FLATBUSH AVE.
BROOKLYN, NY 11238-0000

**Registration No :** 019339
**Date First Registered :** 12/18/86
**Registration Begins :** 01/01/20
**Registered through :** 12/31/22
**Supervisor :** 044958 VAGMAN DMITRY
**Establishment Status :** ACTIVE
**Successor :** NONE

* Use of this online verification service signifies that you have read and agree to the terms and conditions of use. See HELP glossary for further explanations of terms used on this page.

- Use your browser's back key to return to establishment list.
- You may search to see if there has been recent disciplinary action against this registered establishment.

# THE UNIVERSITY OF THE STATE OF NEW YORK
# EDUCATION DEPARTMENT

# NEW YORK STATE BOARD OF PHARMACY

2020-22

SUPERVISING PHARMACIST
DMITRY VAGMAN

THIS IS TO CERTIFY

KINGS PARK SLOPE INC.
357 FLATBUSH AVE.
BROOKLYN, NY 11238

is duly recorded as a

# REGISTERED PHARMACY

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE FIRST DAY OF JANUARY, 2020.
THIS CERTIFICATE EXPIRES ON THE THIRTY-FIRST DAY OF DECEMBER, 2022.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER
019339

Kimberly A. Leonard
EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

1:2
242/656

KINGS PARK SLOPE INC
357 FLATBUSH AVE # 2R
BROOKLYN, NY 11238-4378

10006883 . 2/000258-1/1-0

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| BK0754817 | 12-31-2023 | $888 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N, 3,3N,4,5 | RETAIL PHARMACY | 11-04-2020 |

*KINGS PARK SLOPE INC*
*D/B/A KINGS SUPER PHARMACY*
*357 FLATBUSH AVE*
*BROOKLYN, NY 11238-4378*

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

**THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.**

**CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE**
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KINGS PARK SLOPE INC
D/B/A KINGS SUPER PHARMACY
357 FLATBUSH AVE
BROOKLYN, NY 11238-4378

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Form DEA-223 (9/2016)

**Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)**

## Statement of Responsibility

1. I am the PHARMACIST IN CHARGE (title) for KINGS PARK SLOPE, INC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

DMITRY VAGMAN

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

06/14/2022

Date

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

### Section 1: General Information

Pharmacy Name: Kings Park Slope, LLC

NV Pharmacy or Outsourcing facility license # (if applicable): PH02828

Physical Address: 357 Flatbush Ave

City: Brooklyn State: NY Zip: 11238

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 718-230-3535 Toll Free # (NAC 639.708, NRS 639.23286): 800-795-4647

Fax: 718-230-0596 Contact Email: info@kingsrx.com

Website: www.kingsrx.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Dmitry Vagman

Supervising/Managing Pharmacist NV Pharmacist Registration #: 022297

Name of Person with direct knowledge of compounding procedures: Gennady Levin

Email of Person with direct knowledge of compounding procedures: gene.l@kingsrx.com

Telephone of Person with direct knowledge of compounding procedures: 718-230-3535

**Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)**

1. What risk level sterile compounding will your facility be performing (check all that apply)? ■ Low ■ Medium ■ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ■ Yes ☐ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
Leuprolide
Progesterone Inj

4. Will you be utilizing beyond use dates in excess of USP-797? ■ Yes ☐ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:
We perform the following tests:
* USP 85
* USP 71
* HPLC Chemistry

6. What laboratory performs this additional testing?
Name: Nelson Labs
Address: 122 Fairfield Rd
City: Fairfield State: NJ Zip: 07004
Telephone: 973-227-6882

7. What is your procedure for visual inspection of compounded sterile products?
Inspected against black and white backgrouds

8. How often do you perform glove fingertip and medial fill testing?
Glove fingertip is performed once a week.
Media fill is performed every 6 months.

9. What is your policy if an employee fails a glove fingertip or media-fill test?

Employees exceeding zero CFUs for gloved fingertip/thumb sampling shall be removed from compounding and retrained, observed, and retested. The employee may return to compounding upon passing with zero CFUs for gloved fingertip/thumb sampling.

10. Describe your initial and annual training program for all personnel performing sterile compounding:
All pharmacists and technicians are required to pass the following: didactic coursework; practical skills assessments through competency evaluation; media-fill testing and direct observation by qualified staff, both initially and on an ongoing basis.
IV Ongoing competency evaluation and media-fill testing must, at a minimum, be completed annually for employees working in pharmacies performing low/medium risk level compounding and semiannually for pharmacies performing high risk level compounding.V Personnel who fail written or media-fill tests, will be immediately reinstructed and reevaluated by
expert compounding personnel to ensure correction to all aseptic processes as well as demonstrate the ability to pass repeated written and/or media-fill tests.
VI Failure of follow up written exams requires the re-testing and passing of such tests

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
Perform Cleaning and Maintenance in the following order: 1 Clean/Sanitize the inside surfaces of ISO Class 5 PECs per applicable policy. 2 Discard all trash. 3 Clean/Sanitize the Ante Storage Units a All storage bins must have contents removed; bins cleaned inside and out, allowed to dry and contents replaced. b All surfaces in room including doors, door handles, pass throughs, permanent shelving, etc. 4 Clean/Sanitize the Waste Receptacle(s) 5 Clean/Sanitize Counters and easily cleanable work surfaces in the clean room/buffer area (stool tops, metro cart shelves, etc. (including underside, legs and feet/wheels)). 6 Wipe down equipment 7 Floors will be moped with PeridoxRTU and left to for 3 minutes followed by 70% Sterile Alcohol. 8 Mop floors in the buffer area/clean room from farthest point away from the door progressing toward the door to the ante-area while moving carts and shelving. 9 Counters sink and easily cleanable work surfaces in the ante-area as long as those areas are on the " clean side " of the line of demarcation. 10 Counters and easily cleanable work surfaces in the ante-area/room beyond the line of demarcation ( " dirty side " ). 11 Mop floors in the ante-area/room from the clean room/buffer area entrance to the exit door. 12 Perform any required daily activities related to cleaning the general preparation area as required

12. Who performs the sterile compounding process at your facility?
Gennady Levin, RPh

13. Who is responsible and accountable for the sterile compounding process at your facility?
Gennady Levin

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
See attached

| Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.) | | |
|---|---|---|
| 1. What type of primary engineering controls will you be using in your facility?<br>Biological Safety Cabinet (BSC) | | |
| 2. Is your BSC or CACI vented 100% to the outside? | ■ Yes | ☐ No |
| 3. Do you have a negative pressure buffer room at your facility? | ■ Yes | ☐ No |
| 4. Will you be compounding with antineoplastic HDs or HD API? | ■ Yes | ☐ No |
| 5. If yes, are the drugs stored in an externally ventilated, negative pressure room? | ■ Yes | ☐ No |
| 6. Will you be utilizing a closed system transfer device? | ■ Yes | ☐ No |
| 7. If yes, list the name of the device:<br>Onguard | | |
| 8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?<br>See attached | | |
| 9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?<br>Any personnel who may have contact with a hazardous drug preparation(s) shall complete a formal written training program before working with the preparations. The program shall include at least the following components. A Potential and known risks of the drug preparations B How to handle the drug preparations C How to clean up a hazardous drug spill using hazardous drug spill kits. This includes in the pharmacy, in the delivery vehicle, and in the patient ' s home. D How to use MSDS files E How to interpret warning codes on the labels of hazardous drug preparations F How to store and transport hazardous drug preparations G Proper compounding technique and equipment use for hazardous drug preparations H Proper garb procedures I How to use the eyewash station and safety shower J Proper use of hazardous drug waste containers K Proper labeling of hazardous drug preparations L Proper documentation of the preparation of hazardous drug preparations | | |

**Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)**

1. List the specific high risk sterile products that your facility compounds:
Progesterone in olive oil

2. What sterilization methods are utilized at your facility?
Convection Oven

3. Does your facility utilize biological indicators? ■ Yes ☐ No

4. If yes, describe how they are utilized:
Placed inside the oven during sterilization process

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gennagy Levin
Name of Person who Completed the Form

R Ph
Title

Signature (copies or stamps not accepted)

09/19/2022
Date

| Board Use Only | Date Received:_____ Date Approved:_____ Approved By:_____ |
|---|---|

14. Shipping

Kings maintains processes for selecting appropriate packaging for specific drugs, based on specific medication temperature requirements, light sensitivity of medication, fragility of product, size of product, and manufacturer guidelines.

Medications are packaged to maintain the appropriate temperatures throughout the delivery process; all packages are stable for 24 hours. Refrigerated products are maintained between 2-8°C, (36-46°F) and room temperature products are maintained between 20°C to 25°C (68-77°F). Kings conducts initial and ongoing qualification testing for new packaging products/processes and when products or shipping process are modified, to demonstrate the ability to maintain appropriate temperature ranges and ensure product stability/efficacy. Qualification testing is based on different geographic areas served and different temperature profiles.

8. Hazardous products

Kings Pharmacy provides all patients with education and counseling related to proper handling, storage, and disposal of medications and ancillary supplies, including hazardous drug products/containers. The following information is provided to patients/consumers who receive hazardous products:

Handling:

- Wash hands before and after handling hazardous products

- Use disposable gloves, and examine them to ensure they are not torn or punctured.

- Use disposable medicine cups when handling hazardous pills.

- If using sharps or needles, do not recap the used needle, or remove it from the syringe.

- If you are pregnant or trying to conceive, do not handle any hazardous drugs/products.

Disposal:

- Throw away any protective equipment (e.g. disposable gloves), disposable medicine cups, oral syringes, or bottles in a two-ply heavy-duty trash bag. Tie or seal the plastic bag and place it in your household trash bag for disposal. Be sure to keep this trash out of the reach of pets and children.

- All sharps or needles must be thrown away in a safe 'sharps container.' If you do not have one, use a container made of heavy-duty plastic (e.g. laundry detergent bottle), and close the cap tightly. Containers more than half full should be disposed of at a sharps collection site.

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (04/22/2021)

### Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler KINGS PARK SLOPE, INC

Physical Address 357 FLATBUSH AVE

City BROOKLYN State NY Zip 11579

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 718-230-3535 Website WWW.KINGSRX.COM

Licensing Company Email INFO@KINGSRX.COM

### Section 2: Personal Information

First DMITRY Middle _____ Last VAGMAN

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted] FOX HUNT DRIVE

City MONROE TOWNSHIP State NJ Zip 08831

Telephone [redacted] Email DMITRY.V@KINGSRX.COM

Are you a citizen of the United States? ■ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✔ |



Applicant's initials DV

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| LONG ISLAND UNIVERSITY | | 06/1992-06/1996 | |
| **Address** | **City** | **State** | **Zip** |
| 1 UNIVERSITY PLAZA | BROOKLYN | NY | 11201 |
| Diploma/Degree obtained, if any | | | |
| B. S. PHARMACY | | | |
| School Name | | From - To (MM/YY – MM/YY) | |
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |
| School Name | | From - To (MM/YY – MM/YY) | |
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |
| School Name | | From - To (MM/YY – MM/YY) | |
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |
| School Name | | From - To (MM/YY – MM/YY | |
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 06/2019-PRESENT | [redacted]FOX HUNT DRIVE | MONROE TOWNSHIP | NJ | 08831 |
| 03/2003-06/2019 | [redacted]BUEL AVE | STATEN ISLAND | NY | 10305 |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

Applicant's initials DV

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| KINGS PARK SLOPE, INC | | | 07/2019 - PRESENT | |
| **Business Address** | | **City** | **State** | **Zip** |
| 357 FLATBUSH AVE | | BROOKLYN | NY | 11238 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 718-230-3535 | P.I.C. | | 21,060 | |
| **Description of Duties** | | | | |
| Dispense Prescriptions, Communicate With Prescribers, Ensure Patients' Safety, Counsel Patients, Deal With Insurance Companies, Manage Staff | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

Continue on next page if additional space is needed.

Applicant's initials DV

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✔ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

Applicant's initials _____

I, DMITRY VAGMAN, **certify that as the designated representative for**

KINGS PARK SLOPE, INC,

**that I am qualified as follows and will comply with the following:**

1. I am at least 21 years of age;
3. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. I will serve in this representative capacity for only one pharmacy or wholesaler at a time

DMITRY VAGMAN

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/14/2022

Date

Applicant's initials DV

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

DMITRY VAGMAN

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/14/2022

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of NEW YORK, ss. County of KINGS

I, Dmitry Vagman, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

06/14/2022

**Date**

Subscribed and Sworn to before me this 14 day of June 2022

**Notary Public Signature**

EDWARD GIACOIA
STATE OF NEW YORK
NOTARY PUBLIC
Qualified in QUEENS County
01GI6121549
MY COMMISSION EXPIRES 01/18/2025
(Seal)

Applicant's initials DV

# THE UNIVERSITY OF THE STATE OF NEW YORK

## EDUCATION DEPARTMENT

BE IT KNOWN THAT

# DMITRY VAGMAN

HAVING GIVEN SATISFACTORY EVIDENCE OF THE COMPLETION OF PROFESSIONAL AND OTHER REQUIREMENTS PRESCRIBED BY LAW IS QUALIFIED TO PRACTICE AS A

# PHARMACIST

IN THE STATE OF NEW YORK

IN WITNESS WHEREOF THE EDUCATION DEPARTMENT GRANTS THIS LICENSE UNDER ITS SEAL AT ALBANY, NEW YORK THIS FOURTEENTH DAY OF MARCH, 1997.

LICENSE NUMBER
044958

PRESIDENT OF THE UNIVERSITY
AND COMMISSIONER OF EDUCATION

EXECUTIVE SECRETARY
STATE BOARD OF
PHARMACY

3167452

# 4NN

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Pharmacy Application

**Non-Refundable $500.00 Fee**

Rev (8/02/2022)

| Facility Location | Application Type (check all applicable) | Pharmacy Type (check all applicable) | Services the Pharmacy will Provide (check all applicable) |
|---|---|---|---|
| ☐ Nevada<br>☒ Out-of-State | ☒ New Pharmacy<br>☐ Ownership Change*<br>☐ Location Change *<br>☐ Name Change*<br><br>* If making a change, provide license #:<br><br>PH_____ | ☒ Retail/Community<br>☐ Hospital (# beds _____)<br>☐ Internet<br>☐ Nuclear<br>☐ Other: | ☐ Retail/Community<br>☐ Non-sterile Compounding<br>☐ Sterile Compounding<br>☒ Mail-Order Service<br>☐ Off-site Cognitive Services<br>☐ Long Term Care<br>☐ Hospital<br>☐ Other: |

| Days of Operation | | Ownership Type (check applicable box) |
|---|---|---|
| ☒ Monday | ☒ Friday | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12) |
| ☒ Tuesday | ☐ Saturday | ☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12) |
| ☒ Wednesday | ☐ Sunday | ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12) |
| ☒ Thursday | ☐ Holidays | ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12) |

### Section 1: General Information

Pharmacy Name: Ascension Rx 1001

Physical Address: 7701 Metropolis Drive, Suite 200B

City: Austin State: Texas Zip: 78744

Mailing Address (if different from physical address): 11775 Borman Drive, 2nd Floor

City: Saint Louis State: Missouri Zip: 63146

Telephone: 833-633-7279 Toll Free # (NAC 639.708, NRS 639.23286): 833-329-0634

Fax: 512-969-2727 Contact Email: liv.gamble@ascension.org

Website: N/A

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Brad Jones

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23591

**Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)**

| | |
|---|---|
| Name: Brad Jones | NV Pharmacist Registration #: 23591 |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |

| **Section 3: History of Company** | **Yes** | **No** |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✔ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction? | | ✔ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry? | | ✔ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✔ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✔ |

**If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.**

**Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)**

| | | |
|---|---|---|
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

**Section 5: Publicly Traded Corporation**

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 6: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: Missouri

Parent Company (if any): Ascension Healthcare

Corporation/Organization Name: Ascension Pharmacy Services, LLC

Mailing Address: 11775 Borman Drive, 2nd Floor

City: Saint Louis State: Missouri Zip: 63146

Telephone: 833-633-7279 Email: liv.gamble@ascension.org

Contact Person Name: Liv Gamble

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

**Section 7: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 8: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

**Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)**

**Statement of Responsibility**

1. I am the VP, Chief Pharmacy Officer (title) for Ascension Rx 1001 (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Michael Wescarch

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

6/26/23

Date

**Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding**

## Affidavit for Pharmacy License

I, Michael Wascovich hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the VP, Chief Pharmacy Officer (title) for Ascension Rx 1001 (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 26 day of June, 2023

April L Wood
Notary Public



I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Wascovich

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

6/26/23

Date

| Board Use Only | Date Received: 7/5/23 | Amount: SDO-CK-6373 |
|---|---|---|

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

### Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Ascension Rx Home Delivery

Pharmacy/Wholesaler License # (if applicable): 33772

Physical Address: 7701 Metropolis Drive Bldg 13 Ste 200B

City: Austin State: TX Zip: 78744

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 833-633-7279 Website: ascensionrx.com

Licensing Company Email: ascensionrx@ascension.org

### Section 2: Personal Information

First: Brad Middle: Wynn Last: Jones

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]vy Trellis Trail

City: Del Valley State: TX Zip: 78617

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| University of California San Francisco | | 09/02-06/07 | |
| **Address** | **City** | **State** | **Zip** |
| 505 Parnassus Ave | San Francisco | CA | 94143 |
| **Diploma/Degree obtained, if any** | | | |
| Pharm. D. | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Sacramento State University | | 01/02-09/02 | |
| **Address** | **City** | **State** | **Zip** |
| 6000 J Street | Sacramento | CA | 95819 |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| University of Toledo | | 08/98-12/01 | |
| **Address** | **City** | **State** | **Zip** |
| 2801 W. Bancroft Street | Toledo | OH | 43606 |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| American River College | | 01/96-08/98 | |
| **Address** | **City** | **State** | **Zip** |
| 4700 College Oak Drive | Sacramento | CA | 95841 |
| **Diploma/Degree obtained, if any** | | | |
| Associate Degree | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| Mira Loma High School | | 09/90-06/92 | |
| **Address** | **City** | **State** | **Zip** |
| 4000 Edison Ave | Sacramento | CA | 95821 |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 12/22-present | [redacted]vy Trellis Trail | Del Valley | TX | 78617 |
| 12/21- 12/22 | [redacted]Ramble Lane [redacted] | Austin | TX | 78745 |
| 12/20-12/21 | [redacted] Ambrosia Lane [redacted] | Carlsbad | CA | 92011 |
| 12/18-12/20 | [redacted]Armorlite Drive [redacted] | San Marcos | CA | 92069 |
| 12/16-12/18 | [redacted]Mangano Circle | Encinitas | CA | 92024 |
| 08/13-12/16 | [redacted]Chinquapin Ave [redacted] | Carlsbad | CA | 92008 |
| 08/12-08/13 | [redacted] Adams St [redacted] | Carlsbad | CA | 92008 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Ascension Rx | | | 08/22-Present |
| **Business Address** | **City** | **State** | **Zip** |
| 7701 Metropolis Drive | Austin | TX | 78744 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| 833-633-7279 | Pharmacist | 960 | |
| **Description of Duties** | | | |
| Prescription verification, dispensing, couseling patients on medication use and prescription drug record keeping | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Optum Rx | | | 11/15-01/21 |
| **Business Address** | **City** | **State** | **Zip** |
| 2858 Loker Ave | Carlsbad | CA | 92010 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| 760-804-2222 | Pharmacist | 10,400 | |
| **Description of Duties** | | | |
| Prescription verification, dispensing, fulfillment operations, control drug record keeping and managing and training technicians | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Adecco Medical Staffing | | | 03/15-11/15 |
| **Business Address** | **City** | **State** | **Zip** |
| 701 Palomar Airport Road #300 | Carlsbad | CA | 92011 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| 760-931-8190 | Pharmacist | 800 | |
| **Description of Duties** | | | |
| Prescription verification, dispensing, fulfillment operations and prescription record keeping | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |
| | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

Date

I, Brad Jones, **certify that as the designated representative for**

Ascension Rx Home Delivery 7701 Metropolis Drive Bldg 13 Ste 200B Austin TX 78744,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Brad Jones

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/11/2023

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Brad Jones

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/11/2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Kentucky, ss. County of Boone

I, Liv Gamble Brad Jones, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

04/11/2023

**Date**

Subscribed and Sworn to before me this 11th day of April 2023.

Liv Gamble

**Notary Public Signature**

LIV ERIN GAMBLE
Notary Public
Commonwealth of Kentucky
Commission Number KYNP42609
My Commission Expires Jan 5, 2026

**(Seal)**

Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-500
Austin, TX 78701
512-305-8000

# Inspection Report

## Facility Information

Name: *ASCENSION RX 1001* License Number: *33772*
Class of License: *A*

## Inspection Information

Type: *Compliance* Purpose: *Licensee Request*
Date: *11/03/2021* Arrival Time: *9:45 AM* Departure Time: *10:45 AM*
Action Taken: *Inspection*

## Licenses/Registration

| | |
|---|---|
| Verify personnel have active licenses & address with PIC/RPh if necessary | *Satisfactory* |
| 01. Required licenses posted | *Satisfactory* |
| 09. Active licenses/certifications | *Satisfactory* |
| 62. No aiding and abetting | *Satisfactory* |
| 65. Proper registration procedures | *Satisfactory* |
| 79. Identification badges | *Satisfactory* |

## Inventory Records

| | |
|---|---|
| 15. Change of PIC inventory | *Satisfactory* |

Comment

*Change of PIC inventory completed on: 09/10/2021*

| | |
|---|---|
| 17. Meets inventory requirements | *Satisfactory* |
| 59. Proper drug destruction | *Satisfactory* |
| 68. Change of ownership controlled substance inventory | *Not Applicable* |
| 69. Annual controlled substance inventory | *Satisfactory* |

Comment Due Date for Completed Correction: *12/03/2021*

*Initial controlled substance inventory completed on: 06/21/2021 start (zero c/s)*

## Notifications

| | |
|---|---|
| 31. Closed pharmacy (Is pharmacy engaged in the business described in application for licensure?) | *Not Applicable* |
| 34. Notifications | *Satisfactory* |
| 76. PIC (Does the pharmacy have a pharmacist-in-charge?) | *Satisfactory* |

## Environment/Equipment/Security

| | |
|---|---|
| 03. Orderly/Clean | *Satisfactory* |
| 04. Balance inspection | *Not Applicable* |
| 05. Equipment Inspection | *Satisfactory* |
| 07. Security | *Satisfactory* |
| 08. Environment | *Satisfactory* |
| 48. Drugs (procurement, temperature, security, out-of-date, samples) | *Satisfactory* |
| 90. TSBP complaint notification | *Satisfactory* |

## Controlled Substances

| | |
|---|---|
| 10. Prescriptions separated | *Satisfactory* |
| 24. Theft/Loss | *Satisfactory* |

**Comment**

*No theft or loss has occurred.*

| | |
|---|---|
| 26. Controlled substance prescription compliance | *Satisfactory* |
| 30. Controlled substance invoices dated/initialed by pharmacist | *Satisfactory* |
| 35. Controlled substance invoices separated | *Satisfactory* |
| 46. Drug distribution | *Satisfactory* |
| 53. Possession of controlled substances | *Satisfactory* |
| 57. Corresponding responsibility (Does the pharmacist exercise sound professional judgment with respect to the accuracy or authenticity of a prescription drug order?) | *Satisfactory* |

## Labeling/Prepackaging

| | |
|---|---|
| 32. Prescription label (Is prescription label complete?) | *Satisfactory* |
| 45. Proper dispensing/labeling | *Satisfactory* |
| 54. Proper prepackaging procedures | *Satisfactory* |

## Library

| | |
|---|---|
| 06. Required Library | *Satisfactory* |

## Training

| | |
|---|---|
| 60. Documentation of required training | *Satisfactory* |
| 61. Supervision of supportive personnel | *Satisfactory* |

## Patient/Computer/Dispensing Records

| | |
|---|---|
| 18. Records available | *Satisfactory* |
| 21. Data processing records complete | *Satisfactory* |
| 22. Data processing system compliance | *Satisfactory* |
| 25. Prescriptions (complete, retrievable, auto-refills, accelerated refills) | *Satisfactory* |
| 37. Legal dispensing (Are valid prescriptions being dispensed by a pharmacist?) | *Satisfactory* |
| 56. Prescription transfers | *Satisfactory* |
| 67. Written drug information provided | *Satisfactory* |
| 80. Patient counseling | *Satisfactory* |
| 82. Patient Medication Records | *Satisfactory* |
| 84. Drug regimen review | *Satisfactory* |
| 86. Absence of pharmacist records | *Not Applicable* |

## Policies & Procedures

| | |
|---|---|
| 70. Required policies & procedures | *Satisfactory* |
| 92. Automated dispensing policy & procedures | *Satisfactory* |

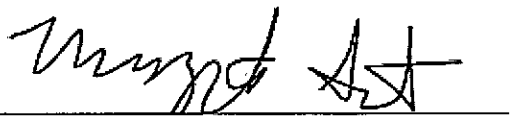
## Non-Sterile Compounding

| | |
|---|---|
| 38. Area for non-sterile compounding | *Not Applicable* |
| 43. Records for non-sterile compounding | *Not Applicable* |

## Signatures

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted.

- Items designated as "Refer to Legal" must be rectified immediately. In addition, the matter discovered during the inspection and deemed to be a serious violation by the inspector will be referred to the Legal Division for review and possible disciplinary action; and
- Items designated as "Warning Notice" must be corrected by the deadline noted to ensure compliance with the laws and rules governing the practice of pharmacy (Note: A "Warning Notice" is issued for a minor violation, and does not equate to disciplinary action).



*Margaret Sant*



*Felicia Carrasco*

Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-500
Austin, TX 78701
512-305-8000

# Notice of Inspection

## Facility Information

Name: *ASCENSION RX 1001*
License Number: *33772*
Address: *7701 METROPOLIS DR STE 200B, AUSTIN, TX 78744*
Phone: *(833) 633-7279*
Email:
Class of License: *A*
License Expiration: *05/31/2023*
DEA #: *FA0293287*
DEA Expiration:

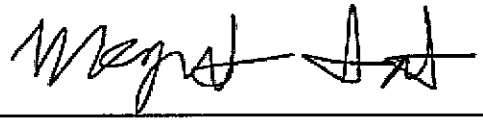
## Inspection Information

Type: *Compliance*
Purpose: *Licensee Request*
Date: *11/03/2021*
Arrival Time: *9:45 AM*

## Acknowledgment

This is to acknowledge that Texas State Board of Pharmacy Agent has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

1. I have read the Notice of Inspection and understand its contents and purpose;
2. I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
3. I have had the purpose of the entry into the above-described facility by the Boards agent stated to me; and
4. I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.



*Margaret Sant, PIC 68817*

## Witnesses



*Felicia Carrasco*

# TEXAS STATE BOARD OF PHARMACY

## Pharmacist in Charge Attestation:

**I hereby attest the following statements are true and accurate (initial each statement below):**

MS — I am the Pharmacist-in-Charge (PIC) of *ASCENSION RX 1001*, pharmacy license number *33772*, and I ☑ was/☐ was not present during a Compliance Inspection conducted by a Texas State Board of Pharmacy Compliance Officer/Inspector on *11/03/2021*.

MS — I received and reviewed the Notice of Inspection, Inspection Report, and Warning Notice (if applicable) issued by the Compliance Officer/Inspector.

MS — I reviewed the document titled Texas State Board of Pharmacy "Red Flags" Checklist for Pharmacies YOU MIGHT BE A PILL MILL IF (on the attestation printout).

N/A — If applicable, the Warning Notice issued contains *0* deficiencies which may require corrections to resolve. I affirm that each of the deficiencies will be corrected by the date noted on the Warning Notice.

MS — I was present and completed this Attestation during the Compliance Inspection.

If not completed during the Compliance Inspection, please mail, email, or fax this completed form to the Board office within 7 days of the date of the inspection:

Texas State Board of Pharmacy
Attn: Compliance Division
333 Guadalupe St. Suite 3-500
Austin. Texas 78701
Email: inspections@pharmacy.texas.gov
Fax: 512-305-8082

**Signed:** Margaret Sant **Date:** *11/03/2021*

**Printed Name:** *Margaret Sant* **License No.(if applicable):** *68817*

**Texas State Board of Pharmacy**
**"Red Flags" Checklist for Pharmacies**
**YOU MIGHT BE A PILL MILL IF...**

*Check all that apply:*

| | |
|---|---|
| | (1) Your pharmacy fills a discernable pattern of prescriptions for prescribers who write essentially the same prescriptions for numerous persons, indicating a lack of individual drug therapy |
| | (2) Your pharmacy operates with limited hours of operation or closes after a certain threshold of controlled substance prescriptions are dispensed, and has overall low prescription dispensing volume. |
| | (3) Prescriptions presented to the pharmacy are for controlled substances with popularity as street drugs, such as opiates, benzodiazepines, muscle relaxants, psychostimulants, and/or cough syrups, or any combination of these drugs. |
| | (4) The prescriptions for controlled substances contain nonspecific or no diagnoses. |
| | (5) The prescriptions are commonly for the highest strength of the drug and/or for large quantities. |
| | (6) Dangerous drugs or OTC products (such as multi-vitamins or laxatives) are added to the controlled substance prescriptions, maintaining relatively consistent 1:1 ratio of controlled substances to dangerous drugs and/or OTC products dispensed as prescriptions. |
| | (7) Prescriptions are authorized by the same prescriber with what appears to be different handwriting on the hardcopy prescription drug order forms. |
| | (8) Upon contact with the prescriber's office, you are unable to engage in comprehensive discussion with the actual prescriber, or he/she is unconcerned about your apprehensions regarding his/her prescribing practices or unwilling to provide additional information, such as treatment goals and/or prognosis with prescribed drug therapy. |
| | (9) You rely solely on the prescriber's representation, or on the representation of the individual answering the phone at the number on the prescription, that prescriptions are legitimate. |
| | (10) The prescriber's clinic is not registered as a pain management clinic by the Texas Medical Board, despite routinely receiving prescriptions from the prescriber foropiates, benzodiazepines, and/or muscle relaxants. |
| | (11) Drugs prescribed are inconsistent with the prescriber's area of practice. |
| | (12) The prescriber of the drugs is located a significant distance from your pharmacy. |
| | (13) The prescriber has been subject to disciplinary action by the licensing board, had his/her DEA registration removed, or been subject to criminal action. |
| | (14) The Texas PMP system indicates that persons are obtaining prescriptions for the same drugs from multiple prescribers or that persons are filling prescriptions for the same drugs at multiple pharmacies. |
| | (15) The person's address is a significant distance from your pharmacy and/or from the prescriber's office. |
| | (16) Multiple persons with the same address present prescriptions from the same prescriber. |
| | (17) Persons pay with cash or credit card more often than through insurance. |
| | (18) Persons presenting controlled substance prescriptions are doing so in such a manner that varies from seeking routine pharmacy services (e.g., willing to wait in long lines to receive drugs, persons arrive in the same vehicle with prescriptions from same prescriber, one person presents to pick up prescriptions for multiple others, persons refer to drugs by "street names" and/or comment on drug's color, persons seek early refills, persons travel from outside reasonable trade area of pharmacy). |
| | (19) Your pharmacy charges and persons are willing to pay more for controlled substances than they would at nearby pharmacies. |
| | (20) Your pharmacy routinely orders controlled substances from more than one drug supplier, or your pharmacy has been discontinued by a drug supplier related to controlled substance orders. |
| | (21) Sporadic and non-consistent dispensing volume (including zero dispensing) varies from day to day and week to week, and your pharmacy does not maintain operational hours each week on Monday through Friday. |
| | (22) Your pharmacy employs or contracts security personnel during operational hours to prevent problems. |
| | (23) Your pharmacy has been previously warned or disciplined by the Texas State Board of Pharmacy for inappropriate dispensing of controlled substances (i.e., corresponding responsibility). |

If you checked any of the above items, you should review the laws and rules regarding corresponding responsibility and non-therapeutic dispensing, especially Board rule §291.29, in the law book or on our website: www.pharmacy.texas.gov (click on Texas Pharmacy Rules and Laws). Additional educational material is available at: http://www.pharmacy.texas.gov/Nontherapeutic.asp. Failure of pharmacies and pharmacists to detect patterns of inappropriate dispensing of prescription drugs is unprofessional practice and constitutes grounds for disciplinary action.

# TEXAS STATE BOARD OF PHARMACY

## Texas Pharmacy License # 33772

## ASCENSION RX 1001

### License Information

**License Status** Active
**License #** 33772
**Expiration Date** 05/31/2025
**Date License Issued** 05/14/2021

### Address

7701 METROPOLIS DR STE 200B
AUSTIN, TX 78744
**County** TRAVIS
**Phone** (833) 633-7279

### Pharmacy Details

**Prior Disciplinary Orders*** No

* Information relating to disciplinary orders is current as of 30 days prior to this date. Please note that disciplinary orders entered more than 10 years ago are not available online. A written request for information regarding prior disciplinary orders may be submitted to the office of the Texas State Board of Pharmacy. Any disciplinary orders entered pursuant to Chapter 564 of the Texas Pharmacy Act are confidential and not subject to public disclosure.

**Class of Pharmacy** Community Pharmacy
**Type of Ownership** LLC
**Type of Pharmacy** Community Independent
**# of Hospital beds**

### Employment Information

**Pharmacist in Charge**
PASCUZZI, ANGELA DIANE

### Pharmacy Profile ¥

| | |
|---|---|
| **Accessible to disabled persons?** | Yes |
| **Participates in the Texas Medicaid program?** | Yes |

**Translating services (Listed Below If Available)**

Spanish
Vietnamese
Telecomm. for the deaf (TDD)

¥ Please note: The data regarding accessibility, translating services, and insurance participation is self-reported by the license holder and no warranty regarding the information is created. Therefore, neither the State of Texas nor the licensing agency accept any legal liability or responsibility or may be held liable or responsible for the accuracy, completeness, timeliness, or usefulness of this information. Should you have any concern as to the accuracy of the data in this system, please contact the license holder or facility for clarification.

### Remedial Plans and Inspection Reports

- 3152278 33772 ASCENSIONRX1001 2021-05 05-2026.pdf
- 3152278 33772 ASCENSIONRX1001 2021-11 11-2026.pdf
- 3152278 33772 ASCENSIONRX1001 2022-07 07-2027.pdf

Remedial Plans and/or Inspection Reports (if any) are shown above and subject to removal at the end of the 5th fiscal year after the Board enters the plan.

### Services Provided

| | |
|---|---|
| **Nuclear** | No |
| **Out-Patient Prescriptions** | Yes |

| | |
|---|---|
| Ship Prescription Out of State | Yes |
| Class D (Expanded Formulary) | No |
| Class D (Alternative Visit Schedule) | No |
| Compounding Sterile-Risk Level Low | No |
| Compounding Sterile-Risk Level Med | No |
| Compounding Sterile-Risk Level High | No |
| Compounding Non-Sterile | No |
| 24 Hour Service | No |
| Closed Door | Yes |
| Compounding, Office Use | No |
| Home Delivery | Yes |
| Infusion | No |
| Pharmacist Administered Immunizations | No |
| Veterinary Prescriptions | No |
| In-Patient Medication Orders | No |
| Out-Patient Surgery | No |
| Rural Hospital | No |
| Tech Check Tech | No |
| 503b Outsourcing Facility | No |
| Other Services | No |

Texas Pharmacist Employment Information

| Pharmacist Name | License # | Registr. Date | Expir. Date | Emp. Status | License Status |
|---|---|---|---|---|---|
| BYERLY, COLTON DAVID | 68480 | 05/13/2021 | 07/31/2025 | Staff | Active |
| CHAN, RENEE | 59776 | 11/03/2016 | 05/31/2024 | Staff | Active |
| CHMIL, BETHANY | 71393 | 09/22/2022 | 05/31/2024 | Staff | Active |
| DOMINGOS, NDINDA ADRIANA | 68572 | 06/17/2021 | 12/31/2024 | Staff | Active |
| DURAN, VANESSA | 64320 | 03/07/2019 | 11/30/2024 | Staff | Active |
| GARZA, DANIELLE ELISE | 68240 | 02/25/2021 | 06/30/2025 | Staff | Active |
| HAWKINS, KATRINA | 63366 | 08/23/2018 | 07/31/2024 | Staff | Active |
| JONES, BRAD WYNN | 70426 | 05/19/2022 | 02/29/2024 | Staff | Active |
| KAZANJIAN, STEPHANIE | 60323 | 03/30/2017 | 11/30/2024 | Staff | Active |
| KIM, YOUNG WAN | 71824 | 12/08/2022 | 02/28/2025 | Staff | Active |
| MEHTA, SURAJ | 69301 | 08/26/2021 | 07/31/2023 | Staff | Active |
| MOORMAN, OFELIA SYLVIA | 26745 | 10/29/1982 | 10/31/2023 | Staff | Active |
| PASCUZZI, ANGELA DIANE | 66949 | 07/23/2020 | 04/30/2024 | PIC | Active |
| PATEL, RUTU | 65649 | 08/29/2019 | 10/31/2023 | Staff | Active |
| PIPKIN, HEATHER DANELLE | 38728 | 08/20/1999 | 08/31/2024 | Staff | Active |
| TALABUCON, CYLENE ANN GARDINER | 69033 | 08/12/2021 | 03/31/2025 | Staff | Active |
| YANG, JENNIFER | 57232 | 08/17/2015 | 05/31/2025 | Staff | Active |

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Texas Registered Technicians/Trainees Employment Information

| Technician/Trainee Name | License # | Registr. Date | Expir. Date | Emp. Status | Reg. Status |
|---|---|---|---|---|---|
| ALANIZ, MARIO E | 120791 | 08/04/2004 | 11/30/2023 | Staff | Active |
| ARENAS, CHRISTIANA VICTORIA | 255124 | 04/20/2016 | 04/30/2025 | Staff | Active |
| BARRERA, JISELA | 260381 | 09/13/2016 | 07/31/2025 | Staff | Active |

| | | | | | |
|---|---|---|---|---|---|
| BARTA, TREY | 211864 | 09/14/2012 | 09/30/2024 | Staff | Active |
| BEACHEM, KEENAN DWAYNE | 242873 | 05/11/2015 | 07/31/2024 | Staff | Active |
| BOLES, KEISHA MONIQUE | 299304 | 08/13/2019 | 08/31/2025 | Staff | Active |
| BUFFINGTON, MICHELLE | 341460 | 07/12/2022 | 07/31/2024 | Staff | Active |
| CASTELLANOS, JOHANNA | 188144 | 07/09/2010 | 10/31/2023 | Staff | Active |
| DELEON, SIXTO | 147108 | 06/01/2007 | 06/30/2025 | Staff | Active |
| DU, ANH CAM | 272317 | 07/18/2017 | 07/31/2025 | Staff | Active |
| GARRETT, ANDREA NICOLE | 187024 | 03/23/2011 | 10/31/2024 | Staff | Active |
| GONZALEZ DE LA TORRE, GABRIELA | 339892 | 05/26/2022 | 05/31/2024 | Staff | Active |
| HARGROVE, WYNTER GRACE | 271492 | 06/21/2017 | 06/30/2025 | Staff | Active |
| HERNANDEZ, BRENDA RUBI | 235909 | 10/13/2014 | 07/31/2024 | Staff | Active |
| JOHN, AYANNA WILHELMINA | 238147 | 12/16/2014 | 10/31/2024 | Staff | Active |
| JONES, CORY MICHAEL | 211780 | 09/06/2012 | 07/31/2024 | Staff | Active |
| LOPEZ-LEDESMA, ABIGAIL | 248738 | 10/16/2015 | 05/31/2025 | Staff | Active |
| LOVE, JASMIN | 259600 | 08/26/2016 | 04/30/2025 | Staff | Active |
| MACON, JILL ANNE | 305689 | 02/17/2020 | 02/29/2024 | Staff | Active |
| MARTINEZ, MICHELLE | 302869 | 11/15/2019 | 11/30/2023 | Staff | Active |

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Texas Remote Pharmacy Information

| Remote Pharmacy Name | Registr. # | Address | City | State | Zipcode |
|---|---|---|---|---|---|

Page 0 of 0 20 No records to view

Texas Pharmacy Owner Information

| Owner Name | Owner Title | Address | City | State | Zipcode |
|---|---|---|---|---|---|
| ASCENSION PHARMACY SERVICES, LLC | OWNER | , | | | |
| WASCOVICH, MICHAEL | OFFICER | , | | | |

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**The Texas State Board of Pharmacy certifies that it maintains the information for the license verification function of this website, performs daily updates to the website, and considers the website to be a secure, primary source for license verification.**

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| FA0293287 | 06-30-2024 | $888 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N,3, 3N,4,5 | RETAIL PHARMACY | 05-19-2021 |

ASCENSION RX 1001
ASCENSION PHARMACY SERVICES, LLC.
7701 METROPOLIS DR STE 200B
AUSTIN, TX 787443125

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

**THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.**

**CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE**
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| FA0293287 | 06-30-2024 | $888 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N,3, 3N,4,5 | RETAIL PHARMACY | 05-19-2021 |

ASCENSION RX 1001
ASCENSION PHARMACY SERVICES, LLC.
7701 METROPOLIS DR STE 200B
AUSTIN, TX 787443125

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

**Texas Pharmacist Employment information**

| Pharmacist Name | License # | Registr. Date | Expir. Date | Emp. Status | License Status |
|---|---|---|---|---|---|
| BUTCHKO, GEORGE | 69664 | 10/14/2021 | 07/31/2023 | Staff | Active |
| CHAN, RENEE | 59776 | 11/03/2016 | 05/31/2024 | Staff | Active |
| DOMINGOS, NDINDA ADRIANA | 68572 | 06/17/2021 | 12/31/2022 | Staff | Active |
| DURAN, VANESSA | 64320 | 03/07/2019 | 11/30/2022 | Staff | Active |
| ELLIOTT, DANIEL STEWART | 68052 | 12/10/2020 | 12/31/2022 | Staff | Active |
| GARZA, DANIELLE ELISE | 68240 | 02/25/2021 | 06/30/2023 | Staff | Active |
| HAWKINS, KATRINA | 63366 | 08/23/2018 | 07/31/2024 | Staff | Active |
| JONES, BRAD WYNN | 70426 | 05/19/2022 | 02/29/2024 | Staff | Active |
| KAZANJIAN, STEPHANIE | 60323 | 03/30/2017 | 11/30/2022 | Staff | Active |
| MEHTA, SURAJ | 69301 | 08/26/2021 | 07/31/2023 | Staff | Active |
| MOORMAN, OFELIA SYLVIA | 26745 | 10/29/1982 | 10/31/2023 | Staff | Active |
| PASCUZZI, ANGELA DIANE | 66949 | 07/23/2020 | 04/30/2024 | PIC | Active |
| PIPKIN, HEATHER DANELLE | 38728 | 08/20/1999 | 08/31/2024 | Staff | Active |
| SANT, MARGARET | 68817 | 07/22/2021 | 08/31/2023 | Staff | Active |
| TRAN, ANDREW | 61215 | 08/10/2017 | 09/30/2023 | Staff | Active |
| TRAN, LILIAN QUAN | 60691 | 07/06/2017 | 02/28/2023 | Staff | Active |
| YANG, JENNIFER | 57232 | 08/17/2015 | 05/31/2023 | Staff | Active |

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

# Office of the Secretary of State

## Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Application for Registration for Ascension Pharmacy Services, LLC (file number 803711019), a MISSOURI, USA, Foreign Limited Liability Company (LLC), was filed in this office on August 03, 2020.

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on March 03, 2023.

Jane Nelson
Secretary of State

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (04/22/2021)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of Pharmacy/MDEG/Wholesaler: Ascension Pharmacy Services, LLC d/b/a Ascension Rx 1001

Physical Address: 7701 Metropolis Drive Suite 200B

City: Austin State: TX Zip: 78744

Mailing Address (if different from physical address): n/a

City: State: Zip:

Telephone: 833-633-7279 Website:

Licensing Company Email: Liv.Gamble@ascension.org

**Section 2: Personal Information**

First: Michael Middle: Patrick Last: Wascovich

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Bald Eagle Dr.

City: Huron State: OH Zip: 44839

Telephone: 833-633-7279 Email: Liv.Gamble@ascension.org

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | ✔ | |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

Date of Service: From: June 1997 to: July 2000

Military Occupation/Specialty: Officer in Charge, Hospital Pharmacy / Biomedical Science Corps

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☑ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✔ |

Applicant's initials: MW

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| University of Florida | | August 2011 - June 2014 | |
| Address | City | State | Zip |
| PO Box 112015 | Gainesville | FL | 32611 |
| Diploma/Degree obtained, if any | | | |
| Doctor of Pharmacy (PharmD) | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Tiffin University | | August 2001 - jJune 2003 | |
| Address | City | State | Zip |
| 155 Miami Street | Tiffin | OH | 44883 |
| Diploma/Degree obtained, if any | | | |
| Master of Buisness Administration (MBA) | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| The Ohio State University | | August 1992 - June 1997 | |
| Address | City | State | Zip |
| 281 W Lane Ave | Columbus | OH | 43210 |
| Diploma/Degree obtained, if any | | | |
| Bachelor of Pharmacy (BPharm) | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 06/18-Current | [redacted] Bald Eagle Drive | Huron | OH | 44839 |
| 08/15- 06/18 | [redacted] Marigold CT | Waxhaw | NC | 28173 |
| 01/07- 08/15 | [redacted] Queen Annes Gate | Westlake | OH | 44145 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Ascension Pharmacy Services, LLC d/b/a Ascension Rx | | | 08/22-Present |
| **Business Address** | **City** | **State** | **Zip** |
| 7701 Metropolis Drive Suite 200B | Austin | TX | 78744 |
| **Phone** | **Title** | | |
| 833-633-7279 | Vice President and Chief Pharmacy Officer | | |
| **Description of Duties** | | | |
| Oversee all enterprise-wide pharmacy services for Ascension Pharmacy Services and Ascension Health | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Premier Incorporated | | | 06/15-08/22 |
| **Business Address** | **City** | **State** | **Zip** |
| 13034 Ballantyne Corporate Place | Charlotte | NC | 28277 |
| **Phone** | **Title** | | |
| 877.777.1552 | Vice President, Field Pharmacy Services | | |
| **Description of Duties** | | | |
| Lead field team with 4000+ health system members for all products, services and programs | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Cleveland Clinic | | | |
| **Business Address** | **City** | **State** | **Zip** |
| 9500 Euclid Ave | Cleveland | OH | 44195 |
| **Phone** | **Title** | | |
| 216.444.2000 | Senior Director, Ambulatory Pharmacy | | |
| **Description of Duties** | | | |
| Directly oversee all ambulatory and specialty pharmacy services for Cleveland Clinic | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |
| | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

Applicant's initials MW

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✔ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

Applicant's initials _____

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

6/1/2023

Date

Applicant's initials MW

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Michael Wascovich

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/1/2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Ohio, ss. County of Erie

I, Michael Wascovich, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

6/1/2023

**Date**

Subscribed and Sworn to before me this 1 day of June, 2023.

**Notary Public Signature**

SARAH RICHARDS
Notary Public
State of Ohio
(Seal) My Comm. Expires
May 2, 2026

Applicant's initials MW

# 400

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Pharmacy Application

## Non-Refundable $500.00 Fee

Rev (8/02/2022)

| Facility Location | Application Type (check all applicable) | Pharmacy Type (check all applicable) | Services the Pharmacy will Provide (check all applicable) |
|---|---|---|---|
| ☐ Nevada | ■ New Pharmacy | ■ Retail/Community | ■ Retail/Community |
| ■ Out-of-State | ☐ Ownership Change* | ☐ Hospital (# beds _____) | ☐ Non-sterile Compounding |
| | ☐ Location Change * | ☐ Internet | ☐ Sterile Compounding |
| | ☐ Name Change* | ☐ Nuclear | ☐ Mail-Order Service |
| | | ☐ Other: | ☐ Off-site Cognitive Services |
| | * If making a change, provide license #: | | ☐ Long Term Care |
| | | | ☐ Hospital |
| | PH_____ | | ☐ Other: |

| Days of Operation | | Ownership Type (check applicable box) |
|---|---|---|
| ■ Monday | ■ Friday | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12) |
| ■ Tuesday | ☐ Saturday | ■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12) |
| ■ Wednesday | ☐ Sunday | ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12) |
| ■ Thursday | ☐ Holidays | ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12) |

## Section 1: General Information

Pharmacy Name: BRIGHTSIDE SPECIALTY PHARMACY

Physical Address: 431 N TUSTIN AVE STE 431-C

City: SANTA ANA State: CA Zip: 92705

Mailing Address (if different from physical address): 431 N TUSTIN AVE STE C

City: SANTA ANA State: CA Zip: 92705

Telephone: 714-707-5115 Toll Free # (NAC 639.708, NRS 639.23286): 888-551-0857

Fax: 714-551-6822 Contact Email: BRIGHTSIDESPECIALTYRX@GMAIL.COM

Website: WWW.BRIGHTSIDESPECIALTYRX.COM

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): JESSICA DIAZ

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23704

**Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)**

| | |
|---|---|
| Name: JESSICA DIAZ | NV Pharmacist Registration #: 23704 |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |

| Section 3: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✓ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction? | | ✓ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry? | | ✓ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✓ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✓ |

**If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.**

**Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)**

| | | |
|---|---|---|
| Name: N/A | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

**Section 5: Publicly Traded Corporation**

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 6: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: CALIFORNIA

Parent Company (if any): _____

Corporation/Organization Name: TYDUS GROUP

Mailing Address: 431 N TUSTIN AVE STE C

City: SANTA ANA State: CA Zip: 92705

Telephone: 714-707-5115 Email: TYDUSGROUP@GMAIL.COM

Contact Person Name: TAN PHAM

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

**Section 7: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 8: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

**Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)**

## Statement of Responsibility

1. I am the CFO (title) for BRIGHTSIDE SPECIALTY PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

TAN PHAM

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

06-16-2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

TAN PHAM

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

06-16-2023

Date

| Board Use Only | Date Received: 6/21/23 | Amount: 500.CC |
|---|---|---|

OUT OF STATE NEW PHARMACY APPLICATION FOR NEVADA

TYDUS GROUP DBA BRIGHTSIDE SPECIALTY PHARMACY

**List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)**

1) **TAN PHAM – CFO**
2) **YONG PHOU - CEO**

OUT OF STATE NEW PHARMACY APPLICATION FOR NEVADA

TYDUS GROUP DBA BRIGHTSIDE SPECIALTY PHARMACY

**List the top four stockholders and their percent ownership. NRS 639.231(3)**

1) **TAN PHAM – 50%**
2) **YONG PHOU – 50%**

OUT OF STATE NEW PHARMACY APPLICATION FOR NEVADA

TYDUS GROUP DBA BRIGHTSIDE SPECIALTY PHARMACY

**List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)**

1) **TAN PHAM – 50%**
2) **YONG PHOU – 50%**

# Secretary of State
## Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

| | |
|---|---|
| **Entity Name:** | TYDUS GROUP |
| **Entity No.:** | 4218681 |
| **Registration Date:** | 12/17/2018 |
| **Entity Type:** | Stock Corporation - CA - General |
| **Formed In:** | CALIFORNIA |
| **Status:** | Active |

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

**IN WITNESS WHEREOF**, I execute this certificate and affix the Great Seal of the State of California this day of April 17, 2023.

**SHIRLEY N. WEBER, PH.D.**
**Secretary of State**

**Certificate No.:** 100745920

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

**Section 1: Pharmacy/Wholesaler Information**

Name of Pharmacy/Wholesaler BRIGHTSIDE SPECIALTY PHARMACY

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 431 N TUSTIN AVE STE C

City SANTA ANA State CA Zip 92705

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 714-707-5115 Website BRIGHTSIDESPECIALTYRX.COM

Licensing Company Email BRIGHTSIDESPECIALTYRX@GMAIL.COM

**Section 2: Personal Information**

First JESSICA Middle _____ Last DIAZ

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ■ F ☐ X

Mailing Address [redacted] E 1st St

City TUSTIN State CA Zip 92780

Telephone [redacted] Email jessicad_982@yahoo.com

Are you a citizen of the United States? ■ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✔ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | From - To (MM/YY – MM/YY) |
|---|---|
| Midwestern University - Glendale campus | 05/19 – 06/22 |

| Address | City | State | Zip |
|---|---|---|---|
| 19555 N 59th Ave | Glendale | AZ | 85308 |

Diploma/Degree obtained, if any: PharmD

| School Name | From - To (MM/YY – MM/YY) |
|---|---|
| Cal State Fullerton University | 08/16 – 01/19 |

| Address | City | State | Zip |
|---|---|---|---|
| 800 N State College Blvd | Fullerton | CA | 92831 |

Diploma/Degree obtained, if any: Chemistry B.A.

| School Name | From - To (MM/YY – MM/YY) |
|---|---|
| Foothill High School | 08/06 – 06/10 |

| Address | City | State | Zip |
|---|---|---|---|
| 19251 Dodge Ave | Santa Ana | CA | 92705 |

Diploma/Degree obtained, if any: High School Diploma

| School Name | From - To (MM/YY – MM/YY) |
|---|---|
| | |

| Address | City | State | Zip |
|---|---|---|---|
| | | | |

Diploma/Degree obtained, if any:

| School Name | From - To (MM/YY – MM/YY) |
|---|---|
| | |

| Address | City | State | Zip |
|---|---|---|---|
| | | | |

Diploma/Degree obtained, if any:

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 06/22 – 06/23 | [redacted] E 1st St | Tustin | CA | 92780 |
| 05/19 – 06/22 | [redacted] W St John Rd #2073 | Glendale | AZ | 85308 |
| 01/10 – 05/19 | [redacted] Pasadena St | Santa Ana | CA | 92705 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Brightside specialty pharmacy | | | 06/22 – Present |
| **Business Address** | **City** | **State** | **Zip** |
| 431 N. Tustin Ave Ste C | Santa Ana | CA | 92705 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| (714) 707-5115 | Pharmacist | 3000 | |
| **Description of Duties** | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Fry's Food & Drug | | | 01/19 – 04/22 |
| **Business Address** | **City** | **State** | **Zip** |
| 744 W Camelback Rd | Phoenix | AZ | 85013 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| (602) 279-9001 | Pharmacist Intern | 3000 | |
| **Description of Duties** | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Walmart | | | 01/18 – 01/19 |
| **Business Address** | **City** | **State** | **Zip** |
| 1120 S Anaheim Blvd | Anaheim | CA | 92805 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| (657) 208-5201 | Pharmacy Tech. | 1000 | |
| **Description of Duties** | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |
| **Description of Duties** | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations: | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

N/A

Original Signature (electronic, copies or stamps not accepted)

6/16/23
Date

I, JESSICA DIAZ, **certify that as the designated representative for**

BRIGHTSIDE SPECIALTY PHARMACY,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. JD I am at least 21 years of age;
3. JD I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JD I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JD I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JD I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JD I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

JESSICA DIAZ

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/16/23

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

JESSICA DIAZ

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/16/23

Date

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**Please have this section completed in the presence of a Notary Public.**

State of California, ss. County of Orange

I, JESSICA DIAZ, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

6/16/23

**Date**

Subscribed and Sworn to before me this 16 day of June, 2023.

**Notary Public Signature**

LILI EVANGELISTA
COMM. #2422901
Notary Public · California
Orange County
My Comm. Expires Oct. 23, 2026

(Seal)

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/13/2022)

### Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler BRIGHTSIDE SPECIALTY PHARMACY

Pharmacy/MDEG/Wholesaler License # (if applicable) CA PERMIT PHY 57437

Physical Address 431 N TUSTIN AVE STE C

City SANTA ANA State CA Zip 92705

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 714-707-5115 Website WWW.BRIGHTSIDESPECIALTYRX.COM

Licensing Company Email TYDUSGROUP@GMAIL.COM

### Section 2: Personal Information

First TAN Middle PHUC Last PHAM

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] SALMON

City IRVINE State CA Zip 92618

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | From - To (MM/YY – MM/YY) |
|---|---|
| WESTERN UNIVERSITY OF HEALTH SCIENCES | 08/2006-06/2010 |

| Address | City | State | Zip |
|---|---|---|---|
| 309 E 2ND ST | POMONA | CA | 91766 |

Diploma/Degree obtained, if any: PHARM. D.

| School Name | From - To (MM/YY – MM/YY) |
|---|---|
| CALIFORNIA STATE UNIVERSITY OF FULLERTON | 08/2003-07/2010 |

| Address | City | State | Zip |
|---|---|---|---|
| 800 N STATE COLLEGE BLVD | FULLERTON | CA | 92831 |

Diploma/Degree obtained, if any: N/A

| School Name | From - To (MM/YY – MM/YY) |
|---|---|
| SAVANNA HIGH SCHOOL | |

| Address | City | State | Zip |
|---|---|---|---|
| 301 N GILBERT ST | ANAHEIM | CA | 92801 |

Diploma/Degree obtained, if any: HIGH SCHOOL DIPLOMA

| School Name | From - To (MM/YY – MM/YY) |
|---|---|
| | |

| Address | City | State | Zip |
|---|---|---|---|
| | | | |

Diploma/Degree obtained, if any:

| School Name | From - To (MM/YY – MM/YY |
|---|---|
| | |

| Address | City | State | Zip |
|---|---|---|---|
| | | | |

Diploma/Degree obtained, if any:

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 12/2022-CURRENT | [redacted] SALMON | IRVINE | CA | 92618 |
| 03/2017 - 11/2022 | [redacted]SLAND CORAL | IRVINE | CA | 92618 |
| 10/2015 - 02/2017 | [redacted]W DONOVAN RANCH RD | ANAHEIM | CA | 92804 |
| 06/2012-09/2014 | [redacted]N GARDEN ST | ANAHEIM | CA | 92801 |
| 02/2011-05/2012 | [redacted]ESCALON AVE | SUNNYVALE | CA | 94085 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| TYDUS GROUP DBA BRIGHTSIDE SPECIALTY PHARMACY | | | |
| **Business Address** | **City** | **State** | **Zip** |
| 431 N TUSTIN AVE STE C | SANTA ANA | CA | 92705 |
| **Phone** | **Title** | | |
| 714-707-5115 | CFO | | |
| **Description of Duties** | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| WALGREENS | | 05/2013- 07/2018 | |
| **Business Address** | **City** | **State** | **Zip** |
| 11900 BEACH BLVD | STANTON | CA | 90680 |
| **Phone** | **Title** | | |
| 714-890-9063 | TECH, INTERN, PHARMACIST | | |
| **Description of Duties** | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

06-16-2023
Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Tan Pham

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06-16-2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of California, ss. County of Orange

I, Tan Pham, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

06-16-2023

**Date**

Subscribed and Sworn to before me this 16 day of June, 2023.

**Notary Public Signature**

LILI EVANGELISTA
COMM. #2422901
Notary Public - California
Orange County
My Comm. Expires Oct. 23, 2026

**(Seal)**

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/18/2023)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Brightside Specialty Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PHY 57437

Physical Address: 431 N. Tustin Ave #C

City: Santa Ana State: CA Zip: 92705

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 714-707-5115 Website: www.Brightsidespecialtyrx.com

Licensing Company Email: brightsidespecialtyrx@gmail.com

**Section 2: Personal Information**

First: Yong Middle: Kiet Last: Phou

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]Duane

City: Irvine State: CA Zip: 92620

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Western University of Health Sciences | | | 08/2006- 08/2010 | |
| Address | | City | State | Zip |
| 309 E 2nd street | | Pomona | CA | 91766 |
| Diploma/Degree obtained, if any | | | | |
| Pharm.D | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| California State University, San Bernardino | | | 09/2000- 08/2004 | |
| Address | | City | State | Zip |
| 5500 University Parkway | | San Bernardino | CA | 92407 |
| Diploma/Degree obtained, if any | | | | |
| Bachelors of Science - Chemistry | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| Aquinas High School | | | 09/1996-07/2000 | |
| Address | | City | State | Zip |
| 2772 N. Sterling Ave | | San Bernardino | CA | 92404 |
| Diploma/Degree obtained, if any | | | | |
| Diploma | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |
| School Name | | | From - To (MM/YY – MM/YY | |
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 02/2022- present | [redacted]Duane | Irvine | CA | 92620 |
| 05/2015-02/2022 | [redacted]E. Rutherford Drive | Ontario | CA | 91761 |
| 01/2012-05/2015 | 7[redacted]Sanctuary Drive | Corona | CA | 92883 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Brightside Specialty Pharmacy | | | 09/2019- Present |
| **Business Address** | **City** | **State** | **Zip** |
| 431 N. Tustin Ave | Santa Ana | CA | 92705 |
| **Phone** | **Title** | | |
| 714-707-5115 | Partner | | |
| **Description of Duties** | | | |
| Business Consultant | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Kaiser Permanente | | | 02/2012-07/2019 |
| **Business Address** | **City** | **State** | **Zip** |
| 1301 California St | Redlands | CA | 92374 |
| **Phone** | **Title** | | |
| 833-574-2273 | Pharmacist | | |
| **Description of Duties** | | | |
| Outpatient Pharmacist- Verify prescription orders, prescription transfers, medication consultation | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |
| | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

6/16/23
Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Yong Phou

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/16/23

Date

---

**Please have this section completed in the presence of a Notary Public.**

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuarcy, or validity of that document.

State of California, ss. County of Orange

I, Yong Phou, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

6/16/23

**Date**

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuarcy, or validity of that document.

Subscribed and Sworn to before me this 16th day of June, 2023.

**Notary Public Signature**

JEONGMIN SUH
COMM. # 2359046
NOTARY PUBLIC - CALIFORNIA
ORANGE COUNTY
MY COMM. EXP. MAY 26, 2025

**(Seal)**

**California State Board of Pharmacy**
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

# INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 10/19/2021 Inspector: Elham Delune

Firm: BRIGHTSIDE SPECIALTY PHARMACY Phone: (714) 707-5115

Address: 431 N TUSTIN AVE STE 431-C City: SANTA ANA Zip: 92705

Ownership: CORPORATION

Permit #: PHY57437 Permit Exp: 10/1/2021 DEA#: FT8810384 DEA Exp: 11/30/2022

Date of Self Assessment Form: 11/7/2019 Other Permit #: N/A Date of DEA Inventory: 9/24/2021

Hours M-F: 10AM-6PM Hours Saturday CLOSED Hours Sunday: CLOSED

PIC TAN P PHAM RPH64459 Administrator ___

RPH Consultant ___

| Staff RPH Name: | License #: | Staff Name: | License #: |
|---|---|---|---|
| [redacted]G K PHOU | RPH64425 | ELLEN C CEDENO | TCH147928 |

**Inspector Remarks:**

Routine Inspection
Retail open door community pharmacy in a shopping plaza. Hours of operation are Monday-Friday 10am-6pm.
The pharmacy fills on average 40 RX's per day, primarily dispenses HTN, diabetes, mental health and does delivery for near by residence.
The pharmacy typically is staffed 1 RPH and 1 TCH.

**Items Reviewed:**

-Self-Assessment , Permit, Email registered with the Board (brightsidespecialtyrx@gmail.com), Notice to Consumer sign/point to your language sign , Security, Consultation (provide for delivered RX), Staff - name tags, restroom accessible, Policy and Procedures (QA, Theft and Impairment), hot water, Inventory reconciliation report, DEA Biennial and CAIR poster
-Wholesaler: McKesson (primary), IPC Rx, Auburn, API, Smart Source (ABC), Anda, Medisca, ParMed
-R/D: Out-Date Rx
-dispensing system Digital Rx
-compounds creams and gel, test for potency (DynaLabs).

**Education:**

- ~~Discussed BPC 4312~~
- Licensees email addresses: BPC 4013 requires joining the board's email notification list within 60 days of obtaining a license or at the time of renewal.
- Schedule III to V prescriptions faxed to the pharmacy are not valid and have to be taken as oral prescriptions by RPH or sent as electronically transmitted prescription. (Refer to Scripts Newsletter Fall 2015 and BOP website to review guidance on filling electronic and faxed controlled substance RXs).
- CCR 1732.5(b) requires 2 hours of board provided CE course in Law and Ethics. Applies to pharmacist licenses expiring on or after July 1, 2019. Lwebsite CA Board of Pharm CA. Welcome.
- Provided Board Inspection handout
- Please check Board's website for pharmacy related waivers.

**California State Board of Pharmacy**
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

# INSPECTION REPORT

**Licensee Remarks:**

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____

Pharmacist (print) Tan Phan

Inspector (sign) _____

Inspector (print) _____

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

1614

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

Renewal Certificate

# Retail Pharmacy Permit

LICENSE NO. PHY 57437
RECEIPT NO. 22080108

VALID UNTIL OCTOBER 01, 2023

BRIGHTSIDE SPECIALTY PHARMACY
431 N TUSTIN AVE STE 431-C
SANTA ANA CA 92705

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.
This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) administrator or pharmacist-in-charge.
This permit is valid only at the address shown.

07/29/22
07/29/22 The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

FORM WPHPHY (09/30/19) PHY

**California State Board of Pharmacy**
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

June 13, 2023

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, NV 89521

## California State Board of Pharmacy License Verification

This document reflects the license status of the person or entity identified below on this date with the California State Board of Pharmacy. It may be used as prima facie evidence of the facts recited below pursuant to California Business and Professions Code section 162.

**Licensee Name:** BRIGHTSIDE SPECIALTY PHARMACY

**License Type:** PHARMACY

**License Number:** PHY 57437

**Status:** ACTIVE

**Issue Date:** 10/01/2019

**Expiration Date:** 10/01/2023

**Address of Record:** 431 N TUSTIN AVE STE 431-C SANTA ANA, CA 92705

**Disciplinary Action:** NO RECORD OF DISCIPLINARY ACTION

Anne Sodergren
Executive Officer

By

Ann Altamirano
Public Inquiry Analyst
(916) 518-3045
Pharmacy.PublicRecords@dca.ca.gov

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| FT8810384 | 11-30-2025 | $888 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N,3, 3N,4,5 | RETAIL PHARMACY-COLLECTOR | 10-26-2022 |

TYDUS GROUP
DBA BRIGHTSIDE SPECIALTY PHARMACY
431 N TUSTIN AVE STE C
SANTA ANA, CA 927053821

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

**THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.**

**CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE**
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| FT8810384 | 11-30-2025 | $888 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N,3, 3N,4,5 | RETAIL PHARMACY-COLLECTOR | 10-26-2022 |

TYDUS GROUP
DBA BRIGHTSIDE SPECIALTY PHARMACY
431 N TUSTIN AVE STE C
SANTA ANA, CA 927053821

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| FT8810384 | 11-30-2025 | $888 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N,3, 3N,4,5 | RETAIL PHARMACY-COLLECTOR | 10-26-2022 |

TYDUS GROUP
DBA BRIGHTSIDE SPECIALTY PHARMACY
431 N TUSTIN AVE STE C
SANTA ANA, CA 927053821

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

**THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.**

Form DEA-223/511 (9/2016)

**REPORT**

**CHANGES**

**PROMPTLY**

REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:
   **Drug Enforcement Administration**
   **P.O. Box 2639**
   **Springfield, VA 22152-2639**

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

# 4PP

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Pharmacy Application
## Non-Refundable $500.00 Fee

Rev (8/02/2022)

| Facility Location | Application Type (check all applicable) | Pharmacy Type (check all applicable) | Services the Pharmacy will Provide (check all applicable) |
|---|---|---|---|
| ☐ Nevada | ■ New Pharmacy | ■ Retail/Community | ■ Retail/Community |
| ■ Out-of-State | ☐ Ownership Change* | ☐ Hospital (# beds _____) | ☐ Non-sterile Compounding |
| | ☐ Location Change * | ☐ Internet | ☐ Sterile Compounding |
| | ☐ Name Change* | ☐ Nuclear | ☐ Mail-Order Service |
| | | ☐ Other: | ☐ Off-site Cognitive Services |
| | * If making a change, provide license #: | | ☐ Long Term Care |
| | | | ☐ Hospital |
| | PH_____ | | ☐ Other: |

| Days of Operation | | Ownership Type (check applicable box) |
|---|---|---|
| ■ Monday | ■ Friday | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12) |
| ■ Tuesday | ■ Saturday | ■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12) |
| ■ Wednesday | ☐ Sunday | ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12) |
| ■ Thursday | ☐ Holidays | ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12) |

### Section 1: General Information

Pharmacy Name: Burt's Pharmacy Moorpark

Physical Address: 865 Patriot Dr Ste 103

City: Moorpark State: CA Zip: 93021

Mailing Address (if different from physical address): 2333 Borchard Rd

City: Newbury Park State: CA Zip: 91320

Telephone: 805-552-4500 Toll Free # (NAC 639.708, NRS 639.23286): 855-287-8779

Fax: 805-552-4515 Contact Email: customercare@burtsrx.com

Website: burtsrx.com

Nevada Business License # (if applicable) n/a

Supervising/Managing Pharmacist Name (NRS 639.220): Robert Leark

Supervising/Managing Pharmacist NV Pharmacist Registration #: 22807

**Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)**

| | |
|---|---|
| Name: Robert Leark | NV Pharmacist Registration #: 22807 |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |

| Section 3: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✔ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction? | | ✔ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry? | | ✔ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✔ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✔ |

**If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.**

**Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)**

| | | |
|---|---|---|
| Name: n/a | Credentials: n/a | %: n/a |
| Name: n/a | Credentials: n/a | %: n/a |
| Name: n/a | Credentials: n/a | %: n/a |
| Name: n/a | Credentials: n/a | %: n/a |
| Name: n/a | Credentials: n/a | %: n/a |

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

**Section 5: Publicly Traded Corporation**

State of Incorporation: n/a

Parent Company (if any): n/a

Corporation Name: n/a

Mailing Address: n/a

City: n/a State: n/a Zip: n/a

Telephone: n/a Email: n/a

Contact Person Name: n/a

Date of SEC Registration: n/a | SEC Registration Number: n/a | Stock Exchange Symbol: n/a

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 6: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: CA

Parent Company (if any): n/a

Corporation/Organization Name: Burt's Pharmacy Moorpark, Inc

Mailing Address: 2333 Borchard Rd

City: Newbury Park State: CA Zip: 91320

Telephone: 805-552-4500 Email: customercare@burtsrx.com

Contact Person Name: Robert Leark

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

**Section 7: Partnership**

Partnership Name: n/a

Mailing Address: n/a

City: n/a State: n/a Zip: n/a

Telephone: n/a Email: n/a

Contact Person Name: n/a

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 8: Sole Owner**

Owner's Name: n/a

Business Name: n/a

Business Address: n/a

City: n/a State: n/a Zip: n/a

Telephone: n/a Email: n/a

**Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)**

**Statement of Responsibility**

1. I am the CEO (title) for Burt's Pharmacy Moorpark (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Robert Leark

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

04/06/2023

Date

**Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding**

## Affidavit for Pharmacy License

I, Robert Leark hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CEO (title) for Burt's Pharmacy Moorpark (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 6 day of APRIL, 2023

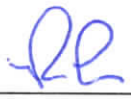
Notary Public

KULDEEP KAUR MANDER
Notary Public - California
Ventura County
Commission # 2442203
My Comm. Expires Mar 25, 2027

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert Leark CEO

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

04/06/2023

Date

| Board Use Only | Date Received: 4-26-23 | Amount: 500.00 CC |
|---|---|---|

**List of All Officers and Directors**

Robert Thomas Leark CEO/CFP/Secretary/Director

**List of All Stockholders**

Robert Thomas Leark 100%

# Secretary of State
## Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

| | |
|---|---|
| **Entity Name:** | Burt's Pharmacy Moorpark, Inc |
| **Entity No.:** | 4191040 |
| **Registration Date:** | 09/10/2018 |
| **Entity Type:** | Stock Corporation - CA - General |
| **Formed In:** | CALIFORNIA |
| **Status:** | Active |

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

**IN WITNESS WHEREOF**, I execute this certificate and affix the Great Seal of the State of California this day of April 06, 2023.

**SHIRLEY N. WEBER, PH.D.**
**Secretary of State**

**Certificate No.:** 097935029

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

**Section 1: Pharmacy/Wholesaler Information**

Name of Pharmacy/Wholesaler Burt's Pharmacy Moorpark

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 865 Patriot Dr. Ste 103

City Moorpark State CA Zip 93021

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (805)552-4500 Website burtsrx.com

Licensing Company Email _____

**Section 2: Personal Information**

First Travis Middle _____ Last Schimmer

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] Simmons Way

City Moorpark State CA Zip 93021

Telephone _____ Email travis@burtsrx.com

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | X |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | X |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Roseman University of Health Sciences | | Aug 2013 - May 2016 | |
| **Address** | **City** | **State** | **Zip** |
| 11 Sunset Way | Henderson | NV | 89014 |
| **Diploma/Degree obtained, if any** | | | |
| Pharm D | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Brigham Young University | | Aug 1998 - April 2005 | |
| **Address** | **City** | **State** | **Zip** |
| 55-220 Kulanui St. | Laie | HI | 96762 |
| **Diploma/Degree obtained, if any** | | | |
| Bachelors of Science | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Moorpark High School | | Aug 1994 - Nov 1996 | |
| **Address** | **City** | **State** | **Zip** |
| 4500 Tierra Rejada Rd | Moorpark | CA | 93021 |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 06/16 – Present | [redacted] Simmons Way | Moorpark | CA | 93021 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| | | | |
|---|---|---|---|
| Business Name: Burts Pharmacy | | | From - To (MM/YY – MM/YY): 04/19 – Present |
| Business Address: 865 Patriot Dr. Ste 103 | City: Moorpark | State: CA | Zip: 93021 |
| Phone: (805) 582-4500 | Title: Pharmacist in charge | | Number of Employed Hours: 6,735+ |
| Description of Duties: Distribute, dispense and keep records of Medications | | | |

| | | | |
|---|---|---|---|
| Business Name: CVS Health | | | From - To (MM/YY – MM/YY): 04/16 – 04/19 |
| Business Address: 155 E. Los Angeles Ave | City: Moorpark | State: CA | Zip: 93021 |
| Phone: (805) 530-0996 | Title: pharmacist | | Number of Employed Hours: 5100+ |
| Description of Duties: Distribute, dispense and keep record of Medications | | | |

| | | | |
|---|---|---|---|
| Business Name: | | | From - To (MM/YY – MM/YY): |
| Business Address: | City: | State: | Zip: |
| Phone: | Title: | | Number of Employed Hours: |
| Description of Duties: | | | |

| | | | |
|---|---|---|---|
| Business Name: | | | From - To (MM/YY – MM/YY): |
| Business Address: | City: | State: | Zip: |
| Phone: | Title: | | Number of Employed Hours: |
| Description of Duties: | | | |

| | | | |
|---|---|---|---|
| Business Name: | | | From - To (MM/YY – MM/YY): |
| Business Address: | City: | State: | Zip: |
| Phone: | Title: | | Number of Employed Hours: |
| Description of Duties: | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | X |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | X |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | X |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | X |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | X |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | X |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | X |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | X |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | X |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Tom Schu
Original Signature (electronic, copies or stamps not accepted)

04/10/2023
Date

I, Travis Schimmer, **certify that as the designated representative for**

_____,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. X I am at least 21 years of age;
3. X I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. X I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. X I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. X I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. X I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Travis Schimmer
Print Name (First, Last)

Travis Schimmer
Original Signature (electronic, copies or stamps not accepted)

04/10/2023
Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Travis Schimmer
Print Name (First, Last)

Travis Schimmer — 4/10/23
Original Signature (electronic, copies or stamps not accepted) — Date

---

**Please have this section completed in the presence of a Notary Public.**

State of California, ss. County of Ventura

I, Travis Schimmer, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Travis Schimmer — 4/10/23
**Original Signature** — **Date**

Subscribed and Sworn to before me this 10 day of April, 2023

**Notary Public Signature**

MILLIE DIAZ
Notary Public - California
Ventura County
Commission # 2339837
My Comm. Expires Dec 9, 2024

State of California County of Ventura, ss.
On 04/10/2023 before me Millie Diaz,
Notary Public, personally appeared Travis Schimmer,
who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument. I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct. WITNESS my hand and official seal.

(Seal)

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/13/2022)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of Pharmacy/MDEG/Wholesaler: Burt's Pharmacy Moorpark

Pharmacy/MDEG/Wholesaler License # (if applicable): n/a

Physical Address: 865 Patriot Dr Ste 103

City: Moorpark State: CA Zip: 93021

Mailing Address (if different from physical address): 2333 Borchard Rd

City: Newbury Park State: CA Zip: 91320

Telephone: 805-552-4500 Website: burtsrx.com

Licensing Company Email: customercare@burtsrx.com

**Section 2: Personal Information**

First: Robert Middle: Thomas Last: Leark

Alias(es, nicknames, name changes, etc.): n/a

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] Avenida Montuoso

City: Thousand Oaks State: CA Zip: 91362

Telephone: [redacted] Email: robbie@burtsrx.com

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| University of Southern California | | 08/03-05/07 | |
| **Address** | **City** | **State** | **Zip** |
| 1985 Zonal Ave | Los Angeles | CA | 90089 |
| **Diploma/Degree obtained, if any** | | | |
| Pharm.D. | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| University of La Verne | | 08/99-5/03 | |
| **Address** | **City** | **State** | **Zip** |
| 1950 3rd St | La Verne | CA | 91750 |
| **Diploma/Degree obtained, if any** | | | |
| BS | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| La Serna High School | | 08/95-06/99 | |
| **Address** | **City** | **State** | **Zip** |
| 15301 Youngwood Dr | Whitter | CA | 90605 |
| **Diploma/Degree obtained, if any** | | | |
| Diploma | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |
| **School Name** | | **From - To (MM/YY – MM/YY** | |
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| n/a | n/a | n/a | n/a | n/a |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Burt's Pharmacy Moorpark | | | 05/18-04/23 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 865 Patriot Dr Ste 103 | | Moorpark | CA | 93021 |
| **Phone** | **Title** | | | |
| 805-552-4500 | CEO/Pharmacist | | | |
| **Description of Duties** | | | | |
| Manager/Pharmacist | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Burt's Specialty Pharmacy | | | 04/20-04/23 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 2628 Conejo Center Dr | | Thousand Oaks | CA | 91320 |
| **Phone** | **Title** | | | |
| 805-375-0300 | CEO | | | |
| **Description of Duties** | | | | |
| CEO | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Cabrillo Pharmacy | | | 11/18-04/23 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 146 N Brent St | | Ventura | CA | 93003 |
| **Phone** | **Title** | | | |
| 805-643-9939 | CEO | | | |
| **Description of Duties** | | | | |
| CEO | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Burt's Pharmacy | | | 04/18-04/23 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 2900 Townsgate Rd Ste 105 | | Westlake Village | CA | 91361 |
| **Phone** | **Title** | | | |
| 805-371-4000 | CEO | | | |
| **Description of Duties** | | | | |
| CEO | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Plaza Pharmacy | | | 07/13-04/23 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 430 E Avenida De Los Arboles Ste103 | | Thousand Oaks | CA | 91360 |
| **Phone** | **Title** | | | |
| 805-492-2451 | CEO | | | |
| **Description of Duties** | | | | |
| CEO | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Burt's Pharmacy | | | 08/09-04/23 | |
| Business Address | | City | State | Zip |
| 2333 Borchard Rd | | Newbury Park | CA | 91320 |
| Phone | Title | | | |
| 805-498-6675 | CEO | | | |
| Description of Duties | | | | |
| CEO/Pharmacist | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| | | | | |
| Phone | Title | | | |
| | | | | |
| Description of Duties | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| | | | | |
| Phone | Title | | | |
| | | | | |
| Description of Duties | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| | | | | |
| Phone | Title | | | |
| | | | | |
| Description of Duties | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | | City | State | Zip |
| | | | | |
| Phone | Title | | | |
| | | | | |
| Description of Duties | | | | |
| | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # n/a. **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| n/a | n/a | n/a | n/a | n/a |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| n/a | | n/a | | |
| **Reason/Charge** | | | | |
| n/a | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| n/a | | | n/a | |
| **Name of Business/Industry/Entity** | | | | |
| n/a | | | | |

**Provide explanation below:**

n/a

Original Signature (electronic, copies or stamps not accepted)

4/6/23
Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Robert Leark

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/06/2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of California, ss. County of Ventura

I, Robert Leark, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

04/06/2023

**Date**

Kuldeep Kaur Mander (Notary Public)

Subscribed and Sworn to before me this 6 day of APRIL, 2023

**Notary Public Signature**

KULDEEP KAUR MANDER
Notary Public - California
Ventura County
Commission # 2442203
My Comm. Expires Mar 25, 2027

**(Seal)**

**California State Board of Pharmacy**
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

# INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 1/14/2020 Inspector: Julia Krumer

Firm: BURT'S PHARMACY MOORPARK Phone: (805) 552-4500

Address: 865 PATRIOT DR STE 103 City: MOORPARK Zip: 93021

Ownership: CORPORATION

Permit #: PHY57125 Permit Exp: 2/1/2021 DEA#: FB8181050 DEA Exp: 7/31/2021

Date of Self Assessment Form: 11/25/2019 Other Permit #: N/A Date of DEA Inventory: 11/20/2019

Hours M-F: 9AM-6PM Hours Saturday 9AM-1PM Hours Sunday: CLOSED

PIC TRAVIS M SCHIMMER RPH75705 Administrator ___

RPH Consultant ___

| Staff | RPH Name: | License #: | Staff Name: | License #: |
|---|---|---|---|---|
| | ROBERT T LEARK -OWNER | RPH60074 | CASEY L BERNARDIN | TCH157821 |
| | ALLEN K TANIGUCHI | RPH30514 | | |

**Inspector Remarks:**

Here for routine inspection at an independent retail pharmacy. Assisted by new PIC Schimmer (since 11/01/2019, change of PIC was submitted to the Board in November 2019).
The pharmacy sell CBD product.
Per PIC Schimmer, the pharmacy does not do any compounding. Sister pharmacy in Newberry park specializes in compounding. Rxs for compounded preparations are transferred and prepared at that location. Most compounded preparations get delivered, some are sent to Moorpark location for patients' pick up.
NTC, Original License & Renewal, and DEA Registration -posted
Pharmacy - Sink Hot/Cold Water- no hot water was available at the time of the inspection. Cold water was available
Restroom-available
Name tags were displayed by all pharmacy personnel
Drug Storage Temperatures - Refrigerator Temperature (36-46F, 2-8C) -thermometer available, temperature is recorded twice daily, log available
Immunization policy, and procedures, CAIR patient forms, Immunization certificate for PIC Schimmer, BLS card for PIC Schimmer-not available. Faxed BLS card for RPH Taniguchi was hard to read.
Policy / Procedure - Technician Job Description, Theft/Impairment/Diversion, QA-available
Temporary Absence of a pharmacist - pharmacist is always on duty.
All Invoices are stored separately
CURES: submitted ion 01/13/2020
No recent DEA106 losses were reported
Use CSOS to order Schedule II medications from Amerisource Bergen
Spot checked shelves for outdates-no outdates were located
Wholesaler- Amerisource Bergen, PARmed
Reverse Distributor- Rx Reverse Distributors
Rx Label - medication descriptions, patient centered labeling – reviewed, "generic for"-available, name of the manufacturer is listed below directions.

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Random prescription books (random controlled and non-controlled)-reviewed, Rx#400331 for Tramadol was written on prescription pad that did not satisfy requirements for controlled substance prescriptions.
Interpretive Services – not available at the time of the inspection
Quality Assurance- no medication errors were reported in the last 12 months.
Consultation - observed during the inspection, provided by PIC Schimmer
Board of Pharmacy Subscriber Email List – available
Schedule II inventory reconciliation report-physical count was compared to quantity on hand kept in the computer system on 11/20/2019 by new PIC Schimmer.

The following were discussed:
1. FDA warning letters and CBD products.
2. Acknowledgement of Schedule II orders with Amerisource Bergen.
3. Electronic faxes for controlled substance (CIII-CV) prescriptions.
4. Schedule II medication reconciliation report to satisfy CCR 1715.65

Education:
1. Medi-Cal pricing (BPC 4425, December 2018 Script)
2. BPC 4113.5-Pharmacy staffing in Community Pharmacy
3. Licensee email addresses (BPC 4013, December 2018 Script)
4. Drug Take back (CCR 1776)
5. Opioid warning Label-Risk of Overdose or Addiction **"Caution: Opioid. Risk of overdose and addiction."**(BPC 4076.7)
6. Patient Co-Pays must charge the lower price (BPC 4079.5)
7. Safe Storage Products if dispense C2-4 (BPC 4106.5)
8. Diabetic Test Strips (BPC 4025.2, BPC 4081 (d), 4301 (t), 4301 (u), October 2017 Script)
9. Board CE webinars and DEA trainings. New Board provided Law and Ethic CE requirements {CCR 1732.5(b)}.
10. ADDS (BPC 4427)

To complete this inspection the following records are being requested by Inspector Krumer. Please fax requested records to **(818)706-1027** or email to :
1. Immunization certificate and BLS card for PIC Schimmer. ✓ 1/21/20 135pm Faxed
2. BLS card for RPH Taniguchi. ✓ 1/21/20 135pm
3. Immunization policy and procedure. ✓ 1/21/20 153pm
4. Policy and procedure addressing interpretive services

**Licensee Remarks:**

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Department of Consumer Affairs
Gavin Newsom, Governor

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____

Pharmacist (print) TRAVIS SCHIMMER

Inspector (sign) _____

Inspector (print) _____

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

# ORDER OF CORRECTION

Date: 1/14/2020 Permit #: PHY57125

Time of Day: 10:27 AM

Name as shown on permit: **BURT'S PHARMACY MOORPARK**

Address: 865 PATRIOT DR STE 103 City: MOORPARK

Please be advised it appears there is a failure to comply with the following laws governing the practice of pharmacy, and/or the rules and regulations of the Board of Pharmacy:

| | |
|---|---|
| 1. CCR 1714(c) | Operational Standards and Security The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes.<br>In that, at the time of the inspection, the pharmacy did not have hot running water. Please provide proof of compliance. |
| 2. H&SC 11162.1(a)( | Prescription Forms for Controlled Substances; Requirements. The prescription forms for controlled substances shall be printed with the following features: Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."<br>In that, dispensed Rx#400331 for Tramadol was written on the prescription form that did not satisfy the requirements for controlled substance. "Prescription is void if the number of drugs prescribed is not noted" was missing. |
| 3. CCR 1707.5(a)(1)( | Patient-Centered Labels for Prescription Drug Containers; Requirements. . Labels on drug containers dispensed to patients in California shall conform to the following format: Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface, and listed in the following order: Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the statement "generic for _____" where the brand name is inserted, and the name of the manufacturer. In the professional judgment of the pharmacist,<br>(i) If the brand name is no longer widely used, the label may list only the generic name of the drug, and<br>(ii) The manufacturer's name may be listed outside of the patient-centered area.<br>In that, at the time of the inspection, the pharmacy prescription label listed name of the drug, "generic for" above the directions; however, the name of the manufacturer was listed below the directions. Please provide proof of compliance. |

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| | |
|---|---|
| 4. CCR 1707.5(d) | Patient-Centered Labels for Prescription Drug Containers; Requirements.. The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.<br><br>In that, at the time of the inspection, the pharmacy did not have policy and procedure addressing help to patients with limited or no English proficiency. Please provide proof of compliance. |
| 5. CCR 1746.4(e) | Pharmacists Initiating and Administering Vaccines. Immunization Registry: A pharmacist shall report, in accordance with section 4052.8, subdivision (b)(3) , of the Business and Professions Code, the information described in section 120440 , subdivision (c), of the Health and Safety Code with in 14 days of the administration of any vaccine. A pharmacist shall inform each patient or the patient's guardian of immunization record sharing preferences, detailed in section 120440, subd ivision (e), of the Health and Safety Code.<br><br>In that, at the time of the inspection, the pharmacy did not have CAIR poster or forms to inform patients about immunization record sharing. Helped to print CAIR forms. |

*I have reviewed, discussed, understand and received a copy of this form.*

Inspector (sign) _____ Signed _____

Inspector (print) _____ Print Name Travis Scrimmer

Date 1/14/2020 Title PIC

Pursuant to Business and Professions Code §4083, a licensee of the California State Board of Pharmacy, may submit a written request within 30 days of service of the order of correction, for an office conference with the board's executive officer to contest the order of correction.

# BOARD OF PHARMACY

## LICENSING DETAILS FOR: PHY 57125

**NAME:** BURT'S PHARMACY MOORPARK

**LICENSE TYPE:** PHARMACY (COMMUNITY)

**LICENSE STATUS:** CLEAR

**ADDRESS**

865 PATRIOT DR STE 103
MOORPARK CA 93021
VENTURA COUNTY

**ISSUANCE DATE**

FEBRUARY 6, 2019

**EXPIRATION DATE**

FEBRUARY 1, 2024

**CURRENT DATE / TIME**

FEBRUARY 13, 2023
10:55:57 AM

## LICENSE RELATIONSHIPS

**NAME:** SCHIMMER, TRAVIS MICHAEL

**ADDRESS NOT DISCLOSED**

**LICENSE/REGISTRATION TYPE:** REGISTERED PHARMACIST

**LICENSE NUMBER:** 75705 **PRIMARY STATUS:** CLEAR

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



April 18, 2023

CPL – California Pharmacy Lawyers
9090 Irvine Center Drive
Irvine, CA 92618

## California State Board of Pharmacy License Verification

This document reflects the license status of the person or entity identified below on this date with the California State Board of Pharmacy. It may be used as prima facie evidence of the facts recited below pursuant to California Business and Professions Code section 162.

**Licensee Name:** BURT'S PHARMACY MOORPARK

**License Type:** PHARMACY

**License Number:** PHY 57125

**Status:** ACTIVE

**Issue Date:** 02/06/2019

**Expiration Date:** 02/01/2024

**Address of Record:** 865 PATRIOT DR STE 103 MOORPARK, CA 93021

**Disciplinary Action:** NO RECORD OF DISCIPLINARY ACTION

Anne Sodergren
Executive Officer

By

Ann Altamirano
Public Inquiry Analyst
(916) 518-3045
Pharmacy.PublicRecords@dca.ca.gov

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| FB8181050 | 07-31-2024 | $888 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N,3, 3N,4,5 | RETAIL PHARMACY | 06-03-2021 |

BURT'S PHARMACY MOORPARK
865 PATRIOT DR., STE. 103
MOORPARK, CA 93021

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

**THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.**

**CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE**
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| FB8181050 | 07-31-2024 | $888 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N,3, 3N,4,5 | RETAIL PHARMACY | 06-03-2021 |

BURT'S PHARMACY MOORPARK
865 PATRIOT DR., STE. 103
MOORPARK, CA 93021

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Form DEA-223 (9/2016)

# 4QQ

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Pharmacy Application
## Non-Refundable $500.00 Fee

Rev (8/02/2022)

| Facility Location | Application Type (check all applicable) | Pharmacy Type (check all applicable) | Services the Pharmacy will Provide (check all applicable) |
|---|---|---|---|
| ☐ Nevada | ☒ New Pharmacy | ☒ Retail/Community | ☒ Retail/Community |
| ☒ Out-of-State | ☐ Ownership Change* | ☐ Hospital (# beds _____) | ☐ Non-sterile Compounding |
| | ☐ Location Change * | ☐ Internet | ☐ Sterile Compounding |
| | ☐ Name Change* | ☐ Nuclear | ☒ Mail-Order Service |
| | | ☐ Other: | ☐ Off-site Cognitive Services |
| | * If making a change, provide license #: | | ☐ Long Term Care |
| | | | ☐ Hospital |
| | PH_____ | | ☐ Other: |

| Days of Operation | | Ownership Type (check applicable box) |
|---|---|---|
| ☒ Monday | ☒ Friday | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12) |
| ☒ Tuesday | ☐ Saturday | ☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12) |
| ☒ Wednesday | ☐ Sunday | ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12) |
| ☒ Thursday | ☐ Holidays | ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12) |

### Section 1: General Information

Pharmacy Name: PRxP of CA, LLC

Physical Address: 4345 E Lowell Street, Suites C & D

City: Ontario State: CA Zip: 91761

Mailing Address (if different from physical address): n/a

City: n/a State: n/a Zip: n/a

Telephone: 888-505-1485 Toll Free # (NAC 639.708, NRS 639.23286): 888-505-1485

Fax: 888-505-1485 Contact Email: info@340bpharm.com

Website: www.340bpharm.com (informational purposes only)

Nevada Business License # (if applicable) n/a

Supervising/Managing Pharmacist Name (NRS 639.220): David S. Duncan

Supervising/Managing Pharmacist NV Pharmacist Registration #: NV: 23419 - CA: RPH 57235

**Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)**

| | |
|---|---|
| Name: David S. Duncan | NV Pharmacist Registration #: 23419 |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |

| Section 3: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✓ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction? | | ✓ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry? | | ✓ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✓ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✓ |

**If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.**

**Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)**

| | | |
|---|---|---|
| Name: n/a | Credentials: | %: |
| Name: n/a | Credentials: | %: |
| Name: n/a | Credentials: | %: |
| Name: n/a | Credentials: | %: |
| Name: n/a | Credentials: | %: |

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

**Section 5: Publicly Traded Corporation**

State of Incorporation: n/a

Parent Company (if any): n/a

Corporation Name: n/a

Mailing Address: n/a

City: n/a State: n/a Zip: n/a

Telephone: n/a Email: n/a

Contact Person Name: n/a

| Date of SEC Registration: n/a | SEC Registration Number: n/a | Stock Exchange Symbol: n/a |
|---|---|---|

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 6: Non-Publicly Traded Corporation or Company** Pharmacy is an LLC, not a corporation.

State of Incorporation/Organization: California/Limited Liability Company

Parent Company (if any): Healthcare Ventures Group LLC

Corporation/Organization Name: PRxP of CA, LLC

Mailing Address: 4345 E Lowell Street, Suites C & D

City: Ontario State: CA Zip: 91761

Telephone: 888-505-1485 Email: cwakefield@340bpharm.com

Contact Person Name: Chris Wakefield

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ■ No

**Section 7: Partnership**

Partnership Name: n/a

Mailing Address: n/a

City: n/a State: n/a Zip: n/a

Telephone: n/a Email: n/a

Contact Person Name: n/a

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 8: Sole Owner**

Owner's Name: n/a

Business Name: n/a

Business Address: n/a

City: n/a State: n/a Zip: n/a

Telephone: n/a Email: n/a

## Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

### Statement of Responsibility

1. I am the Pharmacist In Charge (title) for PRxP of CA LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

David S. Duncan

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

7/20/2023

Date

**Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding**

## Affidavit for Pharmacy License

I, David S. Duncan hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist In Charge (title) for PRxP of CA LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 13th day of July, 2023

Notary Public

C. W. PHILIPPE
COMM. # 2395551
NOTARY PUBLIC - CALIFORNIA
RIVERSIDE COUNTY
COMM. EXPIRES MAR. 10, 2026

**CALIFORNIA JURAT** GOVERNMENT CODE § 8202

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Riverside

Subscribed and sworn to (or affirmed) before me on

this 13th day of July, 20 23, by
*Date* *Month* *Year*

(1) David S. Duncan

(and (2) _____),
*Name(s) of Signer(s)*

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

C. W. PHILIPPE
COMM. # 2395551
NOTARY PUBLIC - CALIFORNIA
RIVERSIDE COUNTY
COMM. EXPIRES MAR. 10, 2026

Signature _____
*Signature of Notary Public*

*Place Notary Seal and/or Stamp Above*

**OPTIONAL**

*Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.*

**Description of Attached Document**

Title or Type of Document: Affidavit for Pharmacy License

Document Date: 07/12/2023 Number of Pages: _____

Signer(s) Other Than Named Above: _____

©2019 National Notary Association

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Chris Wakefield

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Chris Wakefield — 07/04/2023

Original signature of Authorized Person (copies or stamps not accepted) — Date

| Board Use Only | Date Received: 7/25/25 | Amount: 500 - CK - 1191 |
|---|---|---|

# BOARD OF PHARMACY

## LICENSING DETAILS FOR: PHY 55795

**NAME:** PRXP OF CA LLC

**LICENSE TYPE:** PHARMACY (COMMUNITY)

**LICENSE STATUS:** CLEAR

**ADDRESS**

4345 E LOWELL ST STES C & D
ONTARIO CA 91761
SAN BERNARDINO COUNTY

**ISSUANCE DATE**

AUGUST 4, 2017

**EXPIRATION DATE**

AUGUST 1, 2024

**CURRENT DATE / TIME**

JULY 31, 2023
8:52:10 AM

## LICENSE RELATIONSHIPS

**NAME:** DUNCAN, DAVID STEVEN

**ADDRESS NOT DISCLOSED**

**LICENSE/REGISTRATION TYPE:** REGISTERED PHARMACIST

**LICENSE NUMBER:** 57235 **PRIMARY STATUS:** CLEAR

**PRxP of CA LLC**
4345 E Lowell Street, Suites C & D
Ontario, CA 91761
NPI 1154792570 / NCPDP 5660546
EIN 47-5033209
Toll Free Phone & Fax (888) 505-1485
Email info@340bpharm.com

**DIRECT OWNERSHIP 100% of Shares PRxP of CA LLC – Effective 7/05/2017**

**Healthcare Ventures Group LLC**
1145 Broadway St 2nd FL
East McKeesport, PA 15035
EIN 46-5033443
State & Date Incorporated: DE 2/20/2014

**LLC Manager:** **Chris DeCecco Wakefield**
Email: cwakefield@340bpharm.com
Office Mobile: (412) 477-7803
Office Phone/Fax: (412) 357-5163
(Home Address): [redacted] High St
West Newton, PA 15089
(Home Mobile): [redacted]

**Representatives/Staff – PRxP of CA LLC**

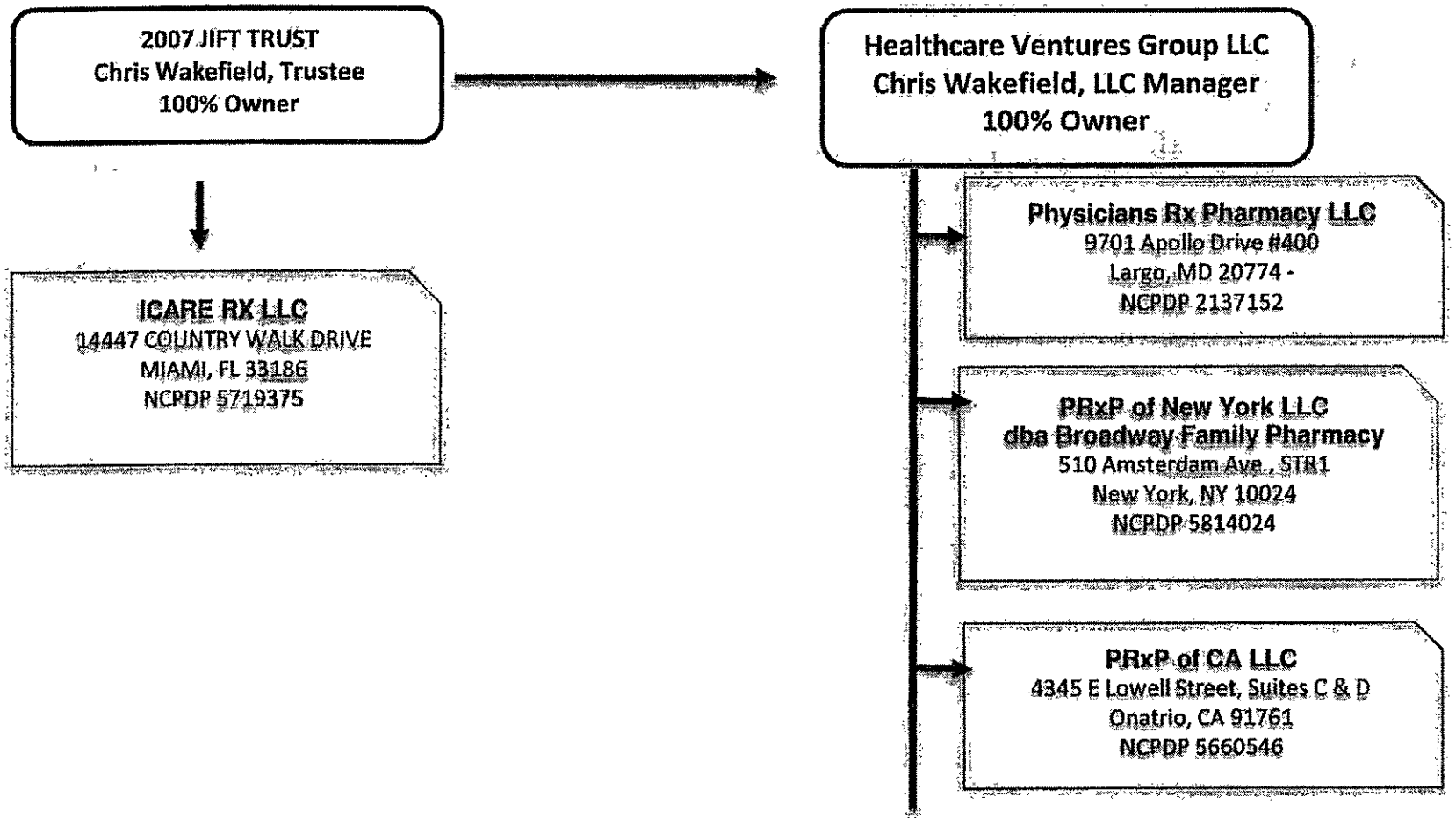
**LLC Manager:** **Chris DeCecco Wakefield**
Email: cwakefield@340bpharm.com
Office Mobile: (412) 477-7803
Office Phone/Fax: (412) 357-5163
(Home Address): [redacted] High St
West Newton, PA 15089
(Home Mobile): [redacted]

**Pharmacist In Charge:** **David S. Duncan**
Email: dduncan@340bpharm.com
Work Phone: (888) 505-1485
(Home Address): [redacted] S McCleve Way E
Ontario, CA 91762
(Home Mobile): [redacted]

**DIRECT OWNERSHIP 100% of Shares HEALTHCARE VENTURES GROUP LLC**

**2007 JIFT Trust**
1193 Beechwood Blvd
Pittsburgh, PA 15206
EIN 25-6906025
State & Date: PA 7/11/2007

| | |
|---|---|
| **Trustee:** | **Chris DeCecco Wakefield** |
| Email: | cwakefield@340bpharm.com |
| Office Mobile: | (412) 477-7803 |
| Office Phone/Fax: | (412) 357-5163 |
| Office Address: | 1145 Broadway St 2nd FL |
| | East McKeesport, PA 15035 |
| (Home Address): | [redacted] High St |
| | West Newton, PA 15089 |
| (Home Mobile): | [redacted] |


2007 JIFT TRUST
Chris Wakefield, Trustee
100% Owner
ICARE RX LLC
14447 COUNTRY WALK DRIVE
MIAMI, FL 33186
NCPDP 5719375
Healthcare Ventures Group LLC
Chris Wakefield, LLC Manager
100% Owner
Physicians Rx Pharmacy LLC
9701 Apollo Drive #400
Largo, MD 20774 -
NCPDP 2137152
PRxP of New York LLC
dba Broadway Family Pharmacy
510 Amsterdam Ave., STR1
New York, NY 10024
NCPDP 5814024
PRxP of CA LLC
4345 E Lowell Street, Suites C & D
Onatrio, CA 91761
NCPDP 5660546

# Secretary of State
## Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

| | |
|---|---|
| **Entity Name:** | PRXP OF CA, LLC |
| **Entity No.:** | 201522910265 |
| **Registration Date:** | 08/14/2015 |
| **Entity Type:** | Limited Liability Company - CA |
| **Formed In:** | CALIFORNIA |
| **Status:** | Active |

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

**IN WITNESS WHEREOF**, I execute this certificate and affix the Great Seal of the State of California this day of July 06, 2023.

**SHIRLEY N. WEBER, PH.D.**
**Secretary of State**

**Certificate No.:** 127543326

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at bizfileOnline.sos.ca.gov.

BA20231071276

# STATE OF CALIFORNIA
*Office of the Secretary of State*
## STATEMENT OF INFORMATION
## LIMITED LIABILITY COMPANY

California Secretary of State
1500 11th Street
Sacramento, California 95814
(916) 653-3516

For Office Use Only

**-FILED-**

File No.: BA20231071276

Date Filed: 7/6/2023

**Entity Details**

| | |
|---|---|
| Limited Liability Company Name | PRXP OF CA, LLC |
| Entity No. | 201522910265 |
| Formed In | CALIFORNIA |

**Street Address of Principal Office of LLC**

| | |
|---|---|
| Principal Address | 1193 BEECHWOOD BLVD<br>PITTSBURGH, PA 15206 |

**Mailing Address of LLC**

| | |
|---|---|
| Mailing Address | 1193 BEECHWOOD BLVD<br>PITTSBURGH, PA 15206 |
| Attention | |

**Street Address of California Office of LLC**

| | |
|---|---|
| Street Address of California Office | None |

**Manager(s) or Member(s)**

| Manager or Member Name | Manager or Member Address |
|---|---|
| ■ Chris Wakefield | 1193 BEECHWOOD BLVD<br>PITTSBURGH, PA 15206 |

**Agent for Service of Process**

| | |
|---|---|
| California Registered Corporate Agent (1505) | VCORP AGENT SERVICES, INC.<br>Registered Corporate 1505 Agent |

**Type of Business**

| | |
|---|---|
| Type of Business | Pharmacy |

**Email Notifications**

| | |
|---|---|
| Opt-in Email Notifications | No, I do NOT want to receive entity notifications via email. I prefer notifications by USPS mail. |

**Chief Executive Officer (CEO)**

| CEO Name | CEO Address |
|---|---|
| None Entered | |

**Labor Judgment**

No Manager or Member, as further defined by California Corporations Code section 17702.09(a)(8), has an outstanding final judgment issued by the Division of Labor Standards Enforcement or a court of law, for which no appeal is pending, for the violation of any wage order or provision of the Labor Code.

**Electronic Signature**

☒ By signing, I affirm under penalty of perjury that the information herein is true and correct and that I am authorized by California law to sign.

*Chris Wakefield* — Signature

*07/06/2023* — Date



B1926-1570 07/06/2023 12:24 PM Received by California Secretary of State

| LLC-1 | Articles of Organization of a Limited Liability Company (LLC) |
|---|---|

201522910265

To form a limited liability company in California, you can fill out this form, and submit for filing along with:

- A $70 filing fee.
- A separate, non-refundable $15 service fee also must be included, if you drop off the completed form.

***Important!*** LLCs in California may have to pay a minimum $800 yearly tax to the California Franchise Tax Board. For more information, go to https://www.ftb.ca.gov.

LLCs may not provide "professional services," as defined by California Corporations Code sections 13401(a) and 13401.3.

Note: *Before submitting the completed form*, you should consult with a private attorney for advice about your specific business needs.

**FILED**
**Secretary of State**
**State of California**
**AUG 14 2015**

1cc

This Space For Office Use Only

**For questions about this form, go to *www.sos.ca.gov/business/be/filing-tips.htm.***

**LLC Name** (List the proposed LLC name exactly as it is to appear on the records of the California Secretary of State.)

① PRxP of CA, LLC
*Proposed LLC Name*

The name must include: LLC, L.L.C., Limited Liability Company, Limited Liability Co., Ltd. Liability Co. or Ltd. Liability Company; and may not include: bank, trust, trustee, incorporated, inc., corporation, or corp., insurer, or insurance company. For general entity name requirements and restrictions, go to www.sos.ca.gov/business/be/name-availability.htm.

**Purpose**

② The purpose of the limited liability company is to engage in any lawful act or activity for which a limited liability company may be organized under the California Revised Uniform Limited Liability Company Act.

**LLC Addresses**

③ a. 11835 W. Olympic Blvd., Suite 900 — Los Angeles — CA — 90064
*Initial Street Address of Designated Office in CA - Do not list a P.O. Box* — *City (no abbreviations)* — *State* — *Zip*

b. _____
*Initial Mailing Address of LLC, if different from 3a* — *City (no abbreviations)* — *State* — *Zip*

**Service of Process** (List a California resident or a California registered corporate agent that agrees to be your initial agent to accept service of process in case your LLC is sued. You may list any adult who lives in California. You may not list an LLC as the agent. Do not list an address if the agent is a California registered corporate agent as the address for service of process is already on file.)

④ a. Vcorp Services CA, Inc.
*Agent's Name*

b. _____ — CA
*Agent's Street Address (if agent is not a corporation) - Do not list a P.O. Box* — *City (no abbreviations)* — *State* — *Zip*

**Management** (Check only one.)

⑤ The LLC will be managed by:

☑ One Manager ☐ More Than One Manager ☐ All Limited Liability Company Member(s)

This form must be signed by each organizer. If you need more space, attach extra pages that are 1-sided and on standard letter-sized paper (8 1/2" x 11"). All attachments are made part of these articles of organization.

Robert E. Fuller
*Organizer - Sign here* — *Print your name here*

Make check/money order payable to: **Secretary of State**
Upon filing, we will return one (1) uncertified copy of your filed document for free, and will certify the copy upon request and payment of a $5 certification fee.

***By Mail***
Secretary of State
Business Entities, P.O. Box 944228
Sacramento, CA 94244-2280

***Drop-Off***
Secretary of State
1500 11th Street, 3rd Floor
Sacramento, CA 95814

I hereby certify that the foregoing transcript of 1 page(s) is a full, true and correct copy of the original record in the custody of the California Secretary of State's office.

AUG 17 2015

Date:

ALEX PADILLA, Secretary of State

# Secretary of State
# Statement of Information
(Limited Liability Company)

**LLC-12**

21-D96303

**FILED**

In the office of the Secretary of State
of the State of California

AUG 04, 2021

**This Space For Office Use Only**

**IMPORTANT** — Read instructions **before completing this form.**

**Filing Fee – $20.00**

**Copy Fees** – First page $1.00; each attachment page $0.50;
Certification Fee - $5.00 plus copy fees

**1. Limited Liability Company Name** (Enter the exact name of the LLC. If you registered in California using an alternate name, see instructions.)

PRXP OF CA, LLC

| 2. 12-Digit Secretary of State File Number | 3. State, Foreign Country or Place of Organization (only if formed outside of California) |
|---|---|
| 201522910265 | CALIFORNIA |

**4. Business Addresses**

| | City (no abbreviations) | State | Zip Code |
|---|---|---|---|
| a. Street Address of Principal Office - Do not list a P.O. Box<br>4345 E LOWELL ST., SUITE C& D | ONTARIO | CA | 91761 |
| b. Mailing Address of LLC, if different than Item 4a<br>1145 Broadway St 2nd FL | EAST MCKEESPORT | PA | 15035 |
| c. Street Address of California Office, if Item 4a is not in California - Do not list a P.O. Box<br>4345 E LOWELL ST., SUITE C& D | ONTARIO | CA | 91761 |

**5. Manager(s) or Member(s)** If no managers have been appointed or elected, provide the name and address of each member. At least one name and address must be listed. If the manager/member is an individual, complete Items 5a and 5c (leave Item 5b blank). If the manager/member is an entity, complete Items 5b and 5c (leave Item 5a blank). Note: The LLC cannot serve as its own manager or member. If the LLC has additional managers/members, enter the name(s) and addresses on Form LLC-12A (see instructions).

| a. First Name, if an individual - Do not complete Item 5b | Middle Name | Last Name | Suffix |
|---|---|---|---|
| Chris | | Wakefield | |
| b. Entity Name - Do not complete Item 5a | | | |
| c. Address | City (no abbreviations) | State | Zip Code |
| 1145 Broadway St 2nd FL | East McKeesport | PA | 15035 |

**6. Service of Process** (Must provide either Individual OR Corporation.)

**INDIVIDUAL** – Complete Items 6a and 6b only. Must include agent's full name and California street address.

| a. California Agent's First Name (if agent is not a corporation) | Middle Name | Last Name | Suffix |
|---|---|---|---|
| b. Street Address (if agent is not a corporation) - Do not enter a P.O. Box | City (no abbreviations) | State | Zip Code |
| | | CA | |

**CORPORATION** – Complete Item 6c only. Only include the name of the registered agent Corporation.

c. California Registered Corporate Agent's Name (if agent is a corporation) – Do not complete Item 6a or 6b

VCORP SERVICES CA, INC. (C3156773)

**7. Type of Business**

a. Describe the type of business or services of the Limited Liability Company

Retail Pharmacy

**8. Chief Executive Officer, if elected or appointed**

| a. First Name | Middle Name | Last Name | Suffix |
|---|---|---|---|
| b. Address | City (no abbreviations) | State | Zip Code |

**9. The information contained herein, including any attachments, is true and correct.**

| 08/04/2021 | Chris Wakefield | Manager | |
|---|---|---|---|
| Date | Type or Print Name of Person Completing the Form | Title | Signature |

**Return Address (Optional)** (For communication from the Secretary of State related to this document, or if purchasing a copy of the filed document enter the name of a person or company and the mailing address. This information will become public when filed. SEE INSTRUCTIONS BEFORE COMPLETING.)

Name: [ ]

Company:

Address:

City/State/Zip: [ ]



Renewal Certificate

# Retail Pharmacy Permit

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

LICENSE NO. PHY 55795
RECEIPT NO. 31562024

VALID UNTIL AUGUST 01, 2024

PRXP OF CA LLC
4345 E LOWELL ST STES C & D
ONTARIO CA 91761

06/05/23
06/05/23

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.
This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change), administrator or pharmacist-in-charge.
This permit is valid only at the address shown.

The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

FORM WPHPHY (09/30/19) PHY

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| FP7122182 | 03-31-2026 | $888 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N,3, 3N,4,5 | RETAIL PHARMACY | 03-15-2023 |

PRXP OF CA LLC
PRXP OF CA LLC
4345 E LOWELL ST
STE C & D
ONTARIO, CA 917612222

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

**THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.**

**CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE**
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| FP7122182 | 03-31-2026 | $888 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N,3, 3N,4,5 | RETAIL PHARMACY | 03-15-2023 |

PRXP OF CA LLC
PRXP OF CA LLC
4345 E LOWELL ST
STE C & D
ONTARIO, CA 917612222

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

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# National Association of Boards of Pharmacy®
# Verified Pharmacy Program® Inspection Form

| | | | |
|---|---|---|---|
| Pharmacy e-Profile ID: | 1623038 | | Inspection Information |
| Legal Business Name: | PRxP of CA LLC | Conference Call Date: | N/A |
| Doing Business As (DBA): | PRxP of CA LLC | Start Time: 24-hour format (13:00) | |
| Address: | 4345 E Lowell St., Ste C & D | End Time: 24-hour format (13:00) | |
| City: | Ontario | Onsite Inspection Date: | 6/8/2023 |
| State: | CA | Start Time: 24-hour format (13:00) | 10:20 |
| Zip Code: | 91761 | End Time: 24-hour format (13:00) | 15:30 |
| Telephone number: | 888/505-1485 | Inspector Name: | Nancy Hall, PharmD |
| Toll free number: | 888/505-1485 | Inspection Performed by (NABP, State, etc): | NABP |
| Fax number: | 888/505-1485 | Observer Name/Affiliation (if applicable): | N/A |
| Website: | www.340Bpharm.com | Observer Name/Affiliation (if applicable): | N/A |

**Pharmacy Hours of Operation** — Check if 24/7: ☐

| | Open | | Closed |
|---|---|---|---|
| | Start Time: (24-hour format) | End Time: (24-hour format) | (X) |
| Sunday | | | X |
| Monday | 9:00 | 17:00 | |
| Tuesday | 9:00 | 17:00 | |
| Wednesday | 9:00 | 17:00 | |
| Thursday | 9:00 | 17:00 | |
| Friday | 9:00 | 17:00 | |
| Saturday | | | X |

| Key Pharmacy Personnel | Name | Contact (e-mail) | e-Profile ID |
|---|---|---|---|
| Pharmacist in Charge | David Duncan | dduncan@340bpharm.com | 207244 |
| Nonsterile Compounding Supervisor | N/A | | |
| Sterile Compounding Supervisor | N/A | | |
| Hazardous Compounding Supervisor | N/A | | |

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| Personnel Present at Time of Inspection | Name | Title | License or registration available and current (Y/N) |
|---|---|---|---|
| 1 | David Duncan | PIC | Y |
| 2 | Sanjay Patel | Pharmacist | Y |
| 3 | Annie Pham | Pharmacist | Y |
| 4 | Reem Hadid | Pharmacy Technician | Y |
| 5 | Damaris Uriarte | Pharmacy Technician | Y |
| 6 | N/A | | |
| 7 | | | |
| 8 | | | |
| 9 | | | |
| 10 | | | |

If more than 10, list the first 10 below, then list the title and number (eg: 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks, etc) for the additional personnel present.

**Business Licensure Information for State of Residence and Federal (board of pharmacy, state controlled substance, DEA, FDA, etc)**

| License/Registration Agency | Business Name on License/Registration | License Type/Number | Expiration Date |
|---|---|---|---|
| CA Board of Pharmacy | PRxP of CA LLC | Retail Pharmacy Permit/PHY 55795 | 8/1/2024 |
| US DOJ/DEA | PRxP of CA LLC dba PRxP of CA LLC | Retail Pharmacy Controlled Substance (CII-CV)/FP7122182 | 3/31/2026 |
| N/A | N/A | N/A | N/A |
| | | | |
| | | | |
| | | | |
| | | | |

Inspector Notes: Nonresident licenses are held in: AZ; CO; IL; IA; MN; MO; MT; NJ; NM; NY; ND; OH; PA; TX; UT; WA; WY. The pharmacy specializes in mail order HIV medications and focuses on the uninsured and underinsured. The majority of patients are covered under the 340B program and some patients are covered by MediCal (Medicaid). They do have occasional local patients who come by to pick up their medications. There are sister PRxP pharmacies in FL, MD, and NY.

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**Attachments**
**(NO PHI, including prescription numbers)**

| Attachment Name | Description |
|---|---|
| N/A | |
| | |
| | |
| | |
| | |

| | Type(s) of practice Type "X" for all that apply | | Type(s) of practice Type "X" for all that apply |
|---|---|---|---|
| Traditional retail | | Telepharmacy | |
| Open to the Public | X | Central Fill/Processing/Shared Services | |
| Closed Door | | Specialty Pharmacy | X |
| Drive-through window | | Handles Medical Marijuana | |
| Mail/Deliver (in state) | X | Nuclear Pharmacy | |
| Mail/Deliver (out-of-state list below) | X | Manufacturer | |
| Veterinary Pharmacy | | Wholesale Distributor | |
| Investigational Drugs, Clinical Trials/Research | | Provide products for "Office Use" | |
| Institutional | | Outsourcing Facility | |
| Long-Term Care | | Nonsterile Compounding | |
| HMO/PBM only | | Nonsterile Hazardous Drug Compounding | |
| Internet Pharmacy (New Rx) | | Sterile Compounding | |
| Internet Pharmacy (Refill Rx) | | Sterile Hazardous Drug Compounding | |

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| Facility Size in Square Feet and Number of PECs | | Personnel | |
|---|---|---|---|
| Total Pharmacy size: | 1200 | Total Pharmacists: | 3 |
| Nonsterile Compounding Room size: | N/A | Number of Compounding Pharmacists | 0 |
| Nonsterile Compounding powder hoods number: | N/A | Total Graduate Students or Residents: | 0 |
| Nonsterile Hazardous Drugs (HD) Compounding Room size: | N/A | Total Student Interns: | 0 |
| Nonsterile HD Compounding BSC/CACI hoods number: | N/A | Total Technicians: | 2 |
| Sterile Compounding Ante Room size: | N/A | Number of Compounding Technicians | 0 |
| Sterile Compounding Clean/Buffer Room size: | N/A | Of technicians, how many are certified? | 1 |
| Sterile Compounding Number LAFW hoods/areas: | N/A | Of technicians, how many are techs-in-training? | 0 |
| Sterile Compounding Number BSC hoods: | N/A | Total Other Licensed Personnel: | 0 |
| Sterile Compounding Number CAI/CACI hoods: | N/A | Total Other Unlicensed Personnel: | 0 |
| Negative Pressure Sterile HD Room size: | N/A | Ratio #tech:#RPh present at time of inspection: | 2:3 |
| Sterile HD Compounding Number of BSC hoods: | N/A | Total Pharmacist Hours Per Week: | 120 |
| Sterile HD Compounding Number of CACI hoods: | N/A | Total Technician Hours Per Week: | 80 |
| **Volume Dispensed** | | **Volume Distributed** | |
| Total Prescriptions Dispensed/day: | 200 | Total Orders Distributed/day: | 0 |
| % Veterinary Prescriptions | 0% | % Veterinary Orders | 0% |
| % Controlled Substance Prescriptions | 0% | % Controlled Substance Orders | 0% |
| % Nonsterile Compounded Prescriptions | 0% | % Nonsterile Compounded Orders | 0% |
| % Sterile Compounded Prescriptions | 0% | % Sterile Compounded Orders | 0% |
| % Hazardous Drugs (HD) Prescriptions | 0% | % Hazardous Drugs (HD) Orders | 0% |

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**Definitions:** DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific, is not labeled with the patient name at the pharmacy.

**States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month):**
Note: if not available, request information be sent to VPP and note that information was requested in grid.

| State | Volume Dispensed | Volume DISTRIBUTED | /day, week, month |
|---|---|---|---|
| Alabama (AL) | | | |
| Alaska (AK) | | | |
| Arizona (AZ) | 234 | 0 | /Month of May |
| Arkansas (AR) | | | |
| California (CA) | 4160 | 0 | /Month of May |
| Colorado (CO) | | | |
| Connecticut (CT) | | | |
| Delaware (DE) | | | |
| District of Columbia (DC) | | | |
| Florida (FL) | | | |
| Georgia (GA) | | | |
| Hawaii (HI) | | | |
| Idaho (ID) | | | |
| Illinois (IL) | 4 | 0 | /Month of May |
| Indiana (IN) | | | |
| Iowa (IA) | | | |
| Kansas (KS) | | | |
| Kentucky (KY) | | | |
| Louisiana (LA) | | | |
| Maine (ME) | | | |
| Maryland (MD) | | | |
| Massachusetts (MA) | | | |
| Michigan (MI) | | | |
| Minnesota (MN) | | | |
| Mississippi (MS) | | | |
| Missouri (MO) | 1 | 0 | /Month of May |
| Montana (MT) | | | |

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**Definitions:** DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific, is not labeled with the patient name at the pharmacy.

**States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month):**
Note: if not available, request information be sent to VPP and note that information was requested in grid.

| State | Volume Dispensed | Volume DISTRIBUTED | /day, week, month |
|---|---|---|---|
| Nebraska (NE) | | | |
| Nevada (NV) | | | |
| New Hampshire (NH) | | | |
| New Jersey (NJ) | 3 | 0 | /Month of May |
| New Mexico (NM) | | | |
| New York (NY) | 19 | 0 | /Month of May |
| North Carolina (NC) | | | |
| North Dakota (ND) | | | |
| Ohio (OH) | | | |
| Oklahoma (OK) | | | |
| Oregon (OR) | | | |
| Pennsylvania (PA) | | | |
| Rhode Island (RI) | | | |
| South Carolina (SC) | | | |
| South Dakota (SD) | | | |
| Tennessee (TN) | | | |
| Texas (TX) | 3 | 0 | /Month of May |
| Utah (UT) | 3 | 0 | /Month of May |
| Vermont (VT) | | | |
| Virginia (VA) | | | |
| Washington (WA) | 4 | 0 | /Month of May |
| West Virginia (WV) | | | |
| Wisconsin (WI) | | | |
| Wyoming (WY) | | | |
| Other | | | |

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# National Association of Boards of Pharmacy®
# Verified Pharmacy Program® Inspection Form

## General Pharmacy Inspection

**The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.**
**An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.**

**Facility Name:** PRxP of CA LLC dba PRxP of CA LLC
**e-Profile ID:** 1623038
**Inspection Date:** 6/8/2023

| | | Finding | Notes |
|---|---|---|---|
| **General Pharmacy** | | | |
| 1.00 | Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.* | Yes | |
| 2.00 | Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite.* | Yes | 40+ hours/week |
| 3.00 | Are there any other businesses located at this address? *If yes, note type of business and name.* | No | |
| 4.00 | Does the pharmacy have any other websites? *Provide list of other names/URLs.* | No | |
| 4.01 | Does the pharmacy hold .pharmacy verification? | No | |
| 5.00 | Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list.* | No | |
| 6.00 | Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)? | No | The patient can send a message to the pharmacy through the website. |
| 7.00 | Are patients able to order or refill prescriptions through the website? *If yes, describe.* | No | The patient can send an email to request a refill. |
| 8.00 | Are photographs allowed during the inspection (no PHI)? | Yes | No photos taken. |
| 9.00 | List of additional personnel **interviewed as part of the inspection, including name and title:** | | Sanjay Patel, RPh |
| **Types of Practice Additional Questions** **If any part of a question is no, enter "No" and explain the observation.** | | | |
| 10.00 | If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.* | No | The pharmacy may ship patient specific medications to a clinic for pick-up by a transient patient, but there is no provider administration of medications. |
| 11.00 | Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.* | No | |
| 12.00 | Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)? | No | |

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| 13.00 | If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.* | N/A | |
| 14.00 | If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.* | N/A | |
| | **General Operations and Licensure**<br>**If any part of a question is no, enter "No" and explain the observation.** | | |
| 15.00 | Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc.* | Yes | Licenses posted and current. |
| 16.00 | Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.* | Yes | 11/3/2021. The same report as submitted with the application. CA BOP usually inspects pharmacies approximately every 3-5 years. |
| 17.00 | Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.* | Yes | The CA BOP issued an order of correction regarding an Rx label translated into Spanish that did not also include the English translation. On 12/1/2021 the pharmacy sent an email to the CA BOP confirming they adjusted their sig codes within the Pioneer Rx software to include both Spanish and English, when required on an Rx label. Other areas of education and information were addressed. The inspector confirmed that labels now printed in Spanish also include the English translation. |
| 18.00 | Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.* | No | |
| 19.00 | Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.* | No | |
| 20.00 | Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.* | No | |
| 21.00 | Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.* | No | |
| 22.00 | Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item.* | No | |
| 23.00 | Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.* | No | |

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| 24.00 | Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.* | No | |
| 25.00 | Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.* | Yes | URAC Specialty and Mail Order 4.0 Accreditation Program valid 9/1/2022-3/1/2025. |
| 26.00 | Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.* | No | |
| 27.00 | Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.* | No | |
| 28.00 | Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?* | Yes | Electronic files maintained on hard drives inside the pharmacy, and the PIC also believes they are backed up to the cloud. Paper files are scanned into the computer for storage. The PIC also saves some of the paper files inside banker boxes and file cabinets within the pharmacy. These would be duplicated in the scanned electronic form. Electronic records are maintained indefinitely. |
| 28.01 | Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?* | Yes | If they were to receive a written or verbal Rx, reduced to writing, they would scan and save it electronically. The PIC states he would likely save the original paper copy, also. The pharmacy receives prescriptions via e-scripts or electronic faxes, and cannot recall the last time they received a paper or verbal Rx since they are a closed door pharmacy. |
| 28.02 | Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).* | Yes | They are maintained electronically on the hard drive in the pharmacy and in the cloud. |
| 28.03 | Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).* | Yes | Dispensing records are saved electronically within the PioneerRx dispensing software and stored on their local hard drive. They also print out a daily report summary, which the PIC signs and saves as a hard copy for at least 7 years. |
| 28.04 | Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).* | Yes | The PioneerRx dispensing software prevents deletion of a record after dispensing. Records are saved electronically on the local hard drive and in the cloud. A daily dispensing report summary is printed and signed by the PIC, then saved in hard copy for at least 7 years. |
| 28.05 | If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable? | N/A | No hard copy records stored off site. Electronic records are also stored to the cloud. |
| 29.00 | Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.* | Yes | Their statement is to follow the most strict laws and regulations. |

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| | | Finding | Notes |
|---|---|---|---|
| | **Personnel** If any part of a question is no, enter "No" and explain the observation. | | |
| 30.00 | Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.* | Yes | The current licenses are posted for each employee. Every month corporate HQ does an OIG search and a SAM disciplinary and exclusion searches for all personnel. They issue the monthly report with the information to the PIC. |
| 31.00 | Is there a process for periodic verification of validity of licenses? *Describe the process.* | Yes | Every month the corporate HQ does an OIG search and SAM disciplinary and exclusion searches for all personnel. They issue the monthly report to the PIC with the information. Monthly the PIC performs a primary source verification (PSV) on the CA BOP website to confirm active licensure for each employee. The PIC also checks monthly PSV for any other states where employees are licensed. |
| 32.00 | If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?* | N/A | |
| 33.00 | Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.* | Yes | Usual daily staffing is 5 employees, 2 Techs to 3 RPh. |
| | **Facility and Security** If any part of a question is no, enter "No" and explain the observation. | | |
| 34.00 | Does the pharmacy have a working security/alarm system in place? *If yes, describe.* | Yes | ADT alarm system including contact alarms on doors, motion detectors, and multiple interior cameras (images viewable to PIC and corporate security). The door has a key lock with an alarm code shared between the pharmacists. If an alarm sounds after hours, ADT calls the PIC and local police. |
| 35.00 | Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.* | Yes | CII-Vs are locked in a wall mounted steel cabinet with a combination lock, inside the pharmacy. Combination limited to the pharmacists. |
| 36.00 | Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.* | Yes | RPh would be on site. Drugs would be inventoried, boxed and transported to the sister pharmacy in NY. Refrigerated items would be sent for destruction. |
| 37.00 | Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.* | Yes | |
| 37.01 | Is the working area well lit and free of tripping hazards? *If no, document with photo.* | Yes | - |
| 37.02 | Is there a sink with hot and cold running water? | Yes | |

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| | | Finding | Notes |
|---|---|---|---|
| 37.03 | If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.* | N/A | No destruction onsite. |
| 37.04 | Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.* | Yes | SMC Returns |
| 37.05 | Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.* | Yes | Hazardous drugs are sent to SMC Returns. They have a spill kit in case of a hazardous spill issue which includes collection of the waste by SMC Returns. The bin is collected as needed. |
| 38.00 | Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.* | Yes | Primarily closed door facility. |
| 39.00 | Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection.* | Yes | The pharmacy temperature is maintained within CRT range. Current: 73.3 degrees F. The system has a caution alarm for temperatures below 68 degrees F and above 77 degrees F, and full excursion alarm below 60 degrees F and above 85 degrees F. Alarms send a text and email to the PIC. |
| 39.01 | Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process* | Yes | The pharmacy has a Sonicu continuous temperature probe monitoring system 24/7/365. There is a Sonicu portal dashboard with full readings and temperature history. The records are maintained in the computer and searchable for historical records. |
| 39.02 | Are excursion action plans in place including evaluating excursion effects on drug product integrity? | Yes | |
| 40.00 | Are the refrigerator and freezer restricted to drug products only (no food)? | Yes | |
| 41.00 | Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?* | Yes | The pharmacy has a Sonicu continuous temperature probe monitoring system 24/7/365. There is a Sonicu portal dashboard with full readings and maintains records and temperature history, maintained indefinitely. Alarms send a text and email to the PIC.<br>Caution alarm range: below 38 degrees F and above 44 degrees F. Full excursion alarm range: below 36 degrees F and above 46 degrees F. |
| 41.01 | Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.* | Yes | 40.1 degrees F |

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| | | Finding | Notes |
|---|---|---|---|
| 42.00 | Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?* | N/A | No frozen drugs. Ice and gel packs only. |
| 42.01 | Is the temperature in the freezer within the USP range (between –25° to –10°C or –13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.* | N/A | |
| 43.00 | Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.* | Yes | For refrigeration failure it is likely items would be sent for destruction. Corporate office is notified of a power outage. As needed the refrigerator would be repaired or replaced. Refrigerated drug dispensing would be transferred to other pharmacies, as needed pending replacement. |
| 44.00 | Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.* | Yes | Have one heat pump for heat and AC. If failure they would call for repair. In case of temperature excursions they would evaluate integrity of drugs and determine disposition and any need for destruction. The PIC has an HVAC repair person who will respond promptly. |
| 45.00 | Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised? | Yes | |
| 46.00 | Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.* | No | |
| 46.01 | If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products? | N/A | |
| | **Product Receipt and Inventory**<br>**If any part of a question is no, enter "No" and explain the observation.** | | |
| 47.00 | Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe.* | Yes | They are a contract pharmacy and some vendors are determined by the covered entity. The pharmacy has a primary agreement with AmerisourceBergen for their retail drugs. The pharmacy requires the vendor is a primary wholesale distributor that sources directly with a manufacturer. |
| 47.01 | Does the pharmacy purchase all prescription drugs directly from the manufacturer? | No | |
| 47.02 | Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase.* | No | |
| 47.03 | Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.* | Yes | AmerisourceBergen, Anda, Capital Wholesale, R+S Northeast. |

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| 47.04 | Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?* | Yes | Per contract agreement, review of transaction data, review of vendor websites. |
| 47.05 | Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)* | No | The PIC reviews direct purchase statements and does monthly spot checks of the wholesale distributors to check the transaction data to ensure the sources are direct from Manfacturer. |
| 47.06 | Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.* | No | The HQ corporate compliance officer ensures the sources are appropriately licensed to ship into CA. |
| 47.07 | Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.* | No | The HQ corporate compliance officer ensures the wholesale distributors reporting to the FDA. |
| 47.08 | Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.* | Yes | The PIC would move the item to the quarantine section, contact the corporate office, contact the sales rep and the vendor for further investigative information. |
| 47.09 | Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.* | Yes | They received an item from R+S Northeast with a stick-on label that identified a different form of the drug. After following the above steps they determined it was a labeling error performed by the vendor. The item was sent back to the vendor. No other agencies notified. |
| 47.10 | Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.* | Yes | Some invoices contain the direct purchase statement. Other vendors require the PIC to go to the vendor portal to check for the transaction data. The PIC performs monthly spot checks on in-bound product transaction data to ensure it is complete. |
| 47.11 | Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting? | Yes | |
| 48.00 | Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?* | No | |
| 49.00 | Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?* | Yes | CSOS access and POA only with one RPh, Sanjay Patel. |
| 50.00 | Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.* | Yes | |

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| 51.00 | Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in? | Yes | |
| 52.00 | Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.* | Yes | Drugs are checked in only with the RPh, the invoice is stamped, dated, quantity checked and signed by the RPh. |
| 53.00 | Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity).* | No | |
| 54.00 | Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).* | Yes | Perpetual inventory of CIIs, monthly count of CIII-V. Perform weekly cycle counts on random drugs with full pharmacy inventory twice a year. |
| 54.01 | Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.* | Yes | Mandatory reporting to CA BOP, law enforcement as needed. No incidents to date. |
| 55.00 | Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)? | Yes | |
| 56.00 | Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.* | Yes | Reconciled monthly. |
| 57.00 | Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).* | Yes | 8/29/2022. DEA inventory performed annually. |
| 57.01 | Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)? | Yes | |
| 58.00 | Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook. | No | |
| 58.01 | Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.* | N/A | |
| 59.00 | Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types.* | No | |
| 59.01 | Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.* | N/A | |

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# National Association of Boards of Pharmacy®
# Verified Pharmacy Program® Inspection Form

## General Pharmacy Inspection

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**e-Profile ID:** 1623038
**Inspection Date:** 6/8/2023

| | | Finding | Notes |
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| 60.00 | Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?* | Yes | Monthly outdate checks for all drugs. Pull drugs 3 months prior to expiry. For some short stocked items there may be an occasion to keep on the shelf closer to expiration date. |
| 60.01 | Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer.* | Yes | |
| 60.02 | How often is active-stock examined for drugs past the expiration date? | | Monthly |
| 61.00 | Does the pharmacy **prepackage** bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?* | No | |
| 62.00 | Does the pharmacy **prepack** multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?* | No | |
| 63.00 | Does the pharmacy return to stock prescription drugs that were filled but never picked up? | N/A | Prescription drugs are mailed/delivered to patients. |
| 63.01 | If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted? | N/A | |
| | **Prescription Processing** If any part of a question is no, enter "No" and explain the observation. | | |
| 64.00 | **Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?* | Yes | Patient profile information is entered by either a pharmacy technician or RPh. Updated with each new Rx or information from prescriber. |
| 64.01 | If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?* | N/A | |
| 65.00 | **Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.* | Yes | The pharmacy receives prescriptions via E-scripts or E-faxes, and prescribers and clinics are well known to the pharmacy. They dispense drugs for known covered entities and have verification of the legitimate Rxs through the entities. |
| 65.01 | Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process.* | Yes | Pharmacy staff would notify the RPh or PIC to make them aware of the issue, then contact the prescriber and covered entity to verify the Rx. The PMP/CURES is consulted for all CS prescriptions. Fraudulent Rxs would not be dispensed and the prescriber and covered entity would be contacted, law enforcement contacted if deemed appropriate. |

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| 65.02 | Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?* | Yes | This is ensured because the pharmacy stays in communication with the covered entities who are directly involved with patient care. Prior authorization is required for some of the medications. The pharmacy requests medical notes, laboratory reports and medical histories, as needed. The prescribers provide the diagnoses codes on the Rxs. Prescribers and health clinics are well known to the pharmacy and many patients are long-term pharmacy customers on maintenance medications. |
| 65.03 | Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.* | Yes | Both. |
| 65.04 | If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations? | Yes | |
| 66.00 | **Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.* | Yes | The pharmacy utilizes a system where three different people handle and lay eyes on each dispensing process. One person enters the Rx information into PioneerRx, another person pulls the label, selects the drug, and fills the Rx, then a third person (a pharmacist) performs both PV1 and PV2 actions as the final check. The original Rx is reviewed at each step. Actions for each step are captured and maintained in the PioneerRx dispensing software. |
| 67.00 | **DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?* | Yes | DURs are triggered in the PioneerRx software at the time of adding new medications to a patient's therapy. The triggered DURs are reviewed and evaluated by the RPh during the PV2 with response and documentation within PioneerRx. |
| 67.01 | Does the DUR include:<br>• drug-drug interaction (Prescription and OTC),<br>• drug-allergy interaction,<br>• therapeutic duplication,<br>• under- or over-utilization (including clinical abuse/misuse),<br>• disease state or condition contraindication,<br>• Incorrect dosage or duration of therapy, and<br>• gender or age related contraindications.<br>*Indicate if there are other parameters routinely included in the DUR.* | Yes | |
| 67.02 | In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe.* | Yes | They may obtain lab results for specific patient and medication requirements. |
| 67.03 | Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates? | Yes | Electronic Clinical Pharmacology. |

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| 67.04 | Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe.* | Yes | Includes zero reporting to nonresident states. Reporting is automatic by the software or may be manual for some states. |
| 67.05 | Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.* | Yes | For all their pharmacy patients they check the PMP/CURES prior to dispensing any CS. |
| 67.06 | Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability.* | Yes | Electronically within PioneerRx. Any additional notes are typed into the patient profile in the patient care notes section. |
| 67.07 | Is the DUR process performed electronically by the computer system? ***Identify integrated drug database used.*** | Yes | Specific database not known. |
| 67.08 | If the DUR is manual, is there a system to document:<br>• How manual DUR is performed<br>• Specific issues that were identified<br>• Pharmacist that considered the identified issues and gave the okay to proceed | N/A | Any manual DUR follow up information is typed into the patient care notes in PioneerRx. |
| 67.09 | If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.* | N/A | |
| 68.00 | Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.* | Yes | PV2 performed by the pharmacist prior to shipping of medication. The action is captured/documented in PioneerRx. |
| 69.00 | Are filled prescriptions appropriately labeled? *Describe.* | Yes | Meets CA labeling requirements for font size and language. |
| 70.00 | **Confidentiality:** Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.* | Yes | PioneerRx |
| 70.01 | Does the pharmacy destroy PHI including labeled prescription vials? | Yes | Shred-It |
| 71.00 | **Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport? | Yes | Including use of specific protective packs for temperature sensitive items with ice packs and gel packs. All meds sent via overnight shipping with UPS or USPS. |

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| 72.00 | **Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.*** | No | |
| 72.01 | If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.* | N/A | |
| 72.02 | If yes, is that location in a different state than this facility? *If so, explain.* | N/A | |
| 72.03 | If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing? | N/A | |
| 73.00 | **Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.* | No | |
| 73.01 | Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?* | N/A | |
| 74.00 | **Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.* | No | |
| 74.01 | If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.* | N/A | |
| 74.02 | Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?* | N/A | |

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| | **Patient Counseling and Communication**<br>If any part of a question is no, enter "No" and explain the observation. | | |
| 75.00 | Does the pharmacist provide counseling for all <u>new</u> prescriptions picked up at the pharmacy (proactively, no "offer")? | Yes | For the rare patients that may come to the pharmacy to pick up their Rxs. |
| 75.01 | Is an "offer" to counsel made for all <u>new</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer".* | N/A | |
| 76.00 | Does the pharmacist provide counseling for all <u>refilled</u> prescriptions picked up at the pharmacy (proactively, no "offer")? | No | |
| 76.01 | Is an "offer" to counsel made for all <u>refilled</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer".* | Yes | PT makes the offer to counsel. Any counseling is by the RPh. |
| 77.00 | Does the pharmacist provide counseling for <u>refilled</u> prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")? | No | |
| 77.01 | Is an "offer" to counsel made for all <u>refilled</u> prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer".* | Yes | PT makes the offer to counsel. Any counseling is by the RPh. |
| 78.00 | Is patient counseling provided for <u>delivered</u> prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.* | Yes | Within each drug shipment the patients get a QR code to scan for specific medication counseling information. The patient is given a 24/7 card with a phone number to call for information. |
| 79.00 | Is patient counseling provided for <u>mailed</u> prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.* | Yes | Within each drug shipment the patients get a QR code to scan for specific medication counseling information. The patient is given a 24/7 card with a phone number to call for information. |
| 80.00 | Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how.* | Yes | Included in hard copy form in the mailed/delivered package. |
| 81.00 | Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how.* | Yes | Included in hard copy form in the mailed/delivered package. |
| 82.00 | Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin, or Tikosyn).* | No | |
| 83.00 | Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how.* | Yes | For the rare patients who come to the pharmacy to pick up their medications, they sign a signature log. |
| 84.00 | Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation).* | Yes | They have a 24 hour telephone number to call which allows the caller to leave a message on 'Cognisent'. 'Cognisent' then transcribes the message into text and notifies the PIC. The PIC gets a text alert from 'Cognisent' with the information and determines the urgency and will return the call, as needed based on urgency. |

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| 85.00 | Are processes in place to handle a drug recall? | Yes | If a recalled item is in stock, they pull the item and follow instructions to return to the vendor or send for destruction. |
| 86.00 | Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program? | No | |
| 86.01 | Does the take-back program include controlled substances? | N/A | |
| 86.02 | Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.* | N/A | |
| | **Quality Assurance/Quality Improvement Program**<br>**If any part of a question is no, enter "No" and explain the observation.** | | |
| 87.00 | Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program.* | Yes | PIC at the pharmacy. There is also an HQ corporate compliance person who has general oversight. |
| 87.01 | Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.* | Yes | Electronic |
| 87.02 | "Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to):<br>1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions;<br>2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse.<br>3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy. | Yes | |
| 87.03 | There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.* | Yes | During the annual employee competencies on the training portal and reviewed at monthly quality meetings. |

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| 88.00 | **Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic.* | Yes | Electronically documented on the quality spreadsheet form. |
| 88.01 | Documentation includes all the pertinent data about the prescription involved including personnel involved at each step. | Yes | |
| 88.02 | Documentation includes documenting the type of QRE details and how/who discovered the QRE. | Yes | |
| 88.03 | Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time. | Yes | |
| 88.04 | Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient. | Yes | |
| 89.00 | **QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc).* | Yes | PIC performs and assesses with each event, then reviewed again at the monthly meeting. |
| 89.01 | The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients. | Yes | |
| 89.02 | For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients. | N/A | |
| 90.00 | **Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support. | Yes | Monthly with staff. |
| 90.01 | The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients. | Yes | |
| 90.02 | Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program. | Yes | |

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| 91.00 | **Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.* | Yes | Would report required or serious issues to the BOP. |
| 91.01 | Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc? | Yes | |
| 91.02 | Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor. | No | Their devices are limited to blood glucometers and if a malfunction, they would guide the patient to the manufacturer for replacement or the pharmacy would replace for the patient. |
| 92.00 | **Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future. | Yes | Performed at the monthly quality meetings. |
| 93.00 | **Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time. | Yes | Survey Q-square links are included with each Rx shipment. Any survey results notify the PIC who can review the comments. |
| 94.00 | **Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program. | Yes | |

| Acronym | Definition |
|---|---|
| ACD | Automated Compounding Device |
| ACOEM | American College of Occupational and Environmental Medicine |
| ACPH | Air Changes Per Hour |
| ADA | Americans with Disabilities Act |
| ADR | Adverse Drug Reaction |
| ALARA | As Low As Reasonably Achievable |
| API | Active Pharmaceutical Ingredient |
| ASHP | American Society of Health-System Pharmacists |
| ASTM | American Society for Testing and Materials |
| AU | Authorized User |
| BOP | Board of Pharmacy |
| BSC | Biological Safety Cabinet |
| BUD | Beyond Use Date |
| CACI | Compounding Aseptic Containment Isolator |
| CAI | Compounding Aseptic Isolator |
| CDC | Center for Disease Control and Prevention |
| CETA | Controlled Environment Testing Association |
| CFR | Code of Federal Regulations |
| CFU | Colony-forming unit |
| CLIA | Clinical Laboratory Improvement Amendment |
| COA | Certificate of Analysis |
| C-PEC | Containment Primary Engineering Control |
| CQI | Continuous Quality Improvement |
| CS | Controlled substance |
| C-SCA | Containment Segregated Compounding Area |
| C-SEC | Containment Secondary Engineering Control |
| CSOS | Controlled Substance Ordering System |
| CSP | Compounded Sterile Preparation |
| CSTD | Closed-System drug-Transfer Device |
| CVE | Containment Ventilated Enclosure |
| DBA | Doing business as |
| DCA | Direct Compounding Area |
| DEA | Drug Enforcement Administration |
| DME | Durable medical equipment |
| DOT | Department of Transportation |
| DUR | Drug Utilization Review |
| EMT | Emergency medical technician |

| | |
|---|---|
| EPA | Environmental Protection Agency |
| FCC | Food Chemicals Codex |
| FDA | Food and Drug Administration |
| GHS | Globally Harmonized System (of classification and labeling of chemicals) |
| HazMat | Hazardous Materials |
| HCS | Hazardous Communication Standard |
| HD | Hazardous Drug |
| HEPA | High Efficiency Particulate Air (filter) |
| HIPAA | Health Insurance Portability and Accountability Act |
| HMO | Health maintenance organization |
| IPA | Isopropyl Alcohol |
| IV | Intravenous |
| LAFW | Laminar Air Flow Workbench |
| LOD | Line of Demarcation |
| MSDS | Material Safety Data Sheet |
| MTM | Medication Therapy Management |
| NF | National Formulary |
| NIOSH | National Institute for Occupational Safety and Health |
| NRC | Nuclear Regulatory Commission |
| NSAID | Non-steroidal anti-inflammatory drug |
| NVLAP | National Voluntary Laboratory Accreditation Program |
| OIG | Office of the Inspector General |
| ONS | Oncology Nursing Society |
| OSHA | Occupational Safety and Health Administration |
| OTC | Over-the-Counter |
| P&P | Policies and Procedures |
| PBM | Pharmacy benefits manager |
| PDMP | Prescription drug monitoring program |
| PEC | Primary Engineering Control |
| PHI | Protected Health Information |
| PIC | Pharmacist-in-charge |
| PMP | Prescription Monitoring Program |
| PPE | Personal Protective Equipment |
| PPI | Patient Package Insert |
| QA | Quality Assurance |
| QI | Quality Improvement |
| QRE | Quality Related Event |
| RAM | Radioactive Material |

| | |
|---|---|
| RCRA | Resource Conservation and Recovery Act |
| REMS | Risk evaluation mitigation strategy |
| RSO | Radiation Safety Officer |
| Rx | Prescription |
| SDS | Safety Data Sheet (formerly MSDS – Material Safety Data Sheet) |
| SOP | Standard Operating Procedure |
| ULPA | Ultra Low Particulate Air (filter) |
| USP | United States Pharmacopeia |
| VAERS | Vaccine Adverse Event Reporting System |
| VFC | Vaccines for Children Program |
| WD | Wholesale distributor |

| Term | Definition |
|---|---|
| Dispense/dispensing | Pursuant to a patient specific prescription, labeled with patient name at the pharmacy |
| Distribute/distributing | Delivered/sent to a practitioner or health care facility for office use or further dispensing, no prescription, not labeled with a patient name at the pharmacy. |
| Type of Practice: Central Fill/Processing/ Shared Services | Where part of the prescription processing and dispensing process occurs at another location |
| Type of Practice: Closed Door | Such as a mail order facility, prescriptions cannot be picked up at the facility, all are sent |
| Type of Practice: HMO/PBM only | Limited to only the beneficiaries of the specific insurance program - no cash patients |
| Type of Practice: Institutional | Such as a hospital or jail |
| Type of Practice: Internet Pharmacy | Pharmacy advertises on the internet, patients fill/refill prescriptions and revise patient profile information on-line. |
| Type of Practice: Investigational Drugs, Clinical Trials or Research | Approved to handle investigational drugs |
| Type of Practice: Long Term Care | Nursing Home pharmacy |
| Type of Practice: Manufacturer | Registered with the FDA as a manufacturer |
| Type of Practice: Open to the Public | Patients are able to come into the pharmacy to pick up filled prescriptions and interact with a pharmacist |
| Type of Practice: Outsourcing Facility | Registered with the FDA as an Outsourcing Facility |
| Type of Practice: Provides Office Use | Distributes prescription and/or compounded preparations to providers for administration or resale. No prescription, not labeled with a patient name by the pharmacy. |
| Type of Practice: Specialty Pharmacy | Business is primarily with specialty drugs and works with specific disease states |
| Type of Practice: Telepharmacy | Pharmacy oversees a remote location staffed by a technician supervised via audio/visual system by a pharmacist at this facility. |
| Type of Practice: Traditional retail | Also known as Community Pharmacy. |
| Type of Practice: Veterinary Pharmacy | Pharmacy business is primarily or exclusively for animals. |
| Type of Practice: Wholesale Distributor | Pharmacy is licensed or registered as a wholesale distributor |

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

### Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler PRxP of CA LLC

Pharmacy/Wholesaler License # (if applicable) California Pharmacy License PHY55795

Physical Address 4345 E Lowell Street, Suites C & D

City Ontario State CA Zip 91761

Mailing Address (if different from physical address) n/a

City n/a State n/a Zip n/a

Telephone 888-505-1485 Website www.340bpharm.com (informational purposes only)

Licensing Company Email info@340bpharm.com

### Section 2: Personal Information

First David Middle S Last Duncan

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] S McCleve Way E

City Ontario State CA Zip 91762

Telephone [redacted] Email dduncan@340bpharm.cm

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| University of the Pacific | | 08/02 - 05/03 | |
| **Address** | **City** | **State** | **Zip** |
| 3601 Pacific Ave | Stockton | CA | 95211 |
| **Diploma/Degree obtained, if any** | | | |
| PharmD | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| California State Unversity, East Bay | | 06/01-09/02 | |
| **Address** | **City** | **State** | **Zip** |
| 25800 Carlos Bee Blvd | Hayward | CA | 94542 |
| **Diploma/Degree obtained, if any** | | | |
| Bachelor of Science, Biology | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Chabot College | | 08/98-03/01 | |
| **Address** | **City** | **State** | **Zip** |
| 25555 Hesperian Blvd | Hayward | CA | 94545 |
| **Diploma/Degree obtained, if any** | | | |
| None | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Palm Springs High School | | 08/91-05/93 | |
| **Address** | **City** | **State** | **Zip** |
| 2401 E Baristo Rd | Palm Springs | CA | 92262 |
| **Diploma/Degree obtained, if any** | | | |
| High School Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Temecula Valley High School | | 08/89-05/91 | |
| **Address** | **City** | **State** | **Zip** |
| 31555 Rancho Vista Rd | Temecula | CA | 92592 |
| **Diploma/Degree obtained, if any** | | | |
| None | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 06/15 - Present | [redacted]S McCleve Way E | Ontario | CA | 91762 |
| 04/09-06/15 | [redacted]Vista Hermosa Dr | Walnut | CA | 91789 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| PRXP of CA LLA | | | 08/22-Present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 4345 E Lowell St Ste C&D | | Ontario | CA | 91761 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 888-505-1485 | Pharmacist in Charge | | 1800 | |

**Description of Duties**
Filling and dispensing prescriptions. Communicating with medical professionals and patients about the medications. Accurately preparing and distributing proper medications to the patients, ordering and receiving medications. PIC duties.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Inland Behavioral Health and Services | | | 06/20-08/22 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 665 N D St | | San Bernardino | CA | 92405 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 909-708-8155 | Lead Pharmacist | | 4160 | |

**Description of Duties**
Filling and dispensing prescriptions. Communicating with medical professionals and patients about the medications. Accurately preparing and distributing proper medications to the patients, ordering and receiving medications. PIC duties.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Good Samaritan Pharmacy | | | 09/19 - 06/20 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 8137 Malachite Ave Ste A | | Rancho Cucamunga | CA | 91730 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 909-774-1115 | Pharmacist in Charge | | 1440 | |

**Description of Duties**
Filling and dispensing prescriptions. Communicating with medical professionals and patients about the medications. Accurately preparing and distributing proper medications to the patients, ordering and receiving medications. PIC duties.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Allmed Staffing / People 2.0 | | | 01/20 - 04/20 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 200 S. Wacker Dr. Suite 3100 | | Chicago | IL | 60606 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 773-254-5555 | Clinical Pharmacist - Per Diem | | 640 | |

**Description of Duties**
Communicating with medical professionals and patients about the medications.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Triad Isotopes/Jubilant Radiopharma | | | 10/16 - 04/19 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 11368 Mountain View Ave Ste B | | Loma Linda | CA | 92354 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 909-253-0734 | Authorized Nuclear Pharmacist | | 4800 | |

**Description of Duties**
Compounded and dispensed radiopharmacueticals

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Rx Relief | | | 05/16 - 10/16 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 740 West Alluvial Ave Ste 101 | | Fresno | CA | 93711 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 800-797-3543 | Relief Pharmacist | | 800 | |

**Description of Duties**
Filling and dispensing prescriptions. Communicating with medical professionals and patients about the medications. Accurately preparing and distributing proper medications to the patients, ordering and receiving medications.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| CVS Health | | | 11/13 - 05/16 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 1127 Bryn Mawr Ave Ste A | | Redlands | CA | 92374 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 909-796-7171 | Pharmacy Supervisor | | 4640 | |

**Description of Duties**
Filling and dispensing prescriptions. Communicating with medical professionals and patients about the medications. Accurately preparing and distributing proper medications to the patients, ordering and receiving medications.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Walgreens | | | 04/06 - 11/13 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 118 E Base Line Rd | | Rialto | CA | 92376 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 909-562-0267 | Pharmacy Manager | | 14560 | |

**Description of Duties**
Filling and dispensing prescriptions. Communicating with medical professionals and patients about the medications. Accurately preparing and distributing proper medications to the patients, ordering and receiving medications. PIC duties.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |

**Description of Duties**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |

**Description of Duties**

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✔ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

Date

I, David S. Duncan, **certify that as the designated representative for**

PRxP of CA LLC,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. DSD I am at least 21 years of age;
3. DSD I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. DSD I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. DSD I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. DSD I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. DSD I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

David Duncan

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7-13-2023

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

David S. Duncan

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7-13-2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of California, ss. County of Riverside

I, David S. Duncan, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

7-13-2023

**Date**

Subscribed and Sworn to before me this 13th day of July.

**Notary Public Signature**

C. W. PHILIPPE
COMM. # 2395551
NOTARY PUBLIC - CALIFORNIA
RIVERSIDE COUNTY
COMM. EXPIRES MAR. 10, 2026

**(Seal)**

**CALIFORNIA JURAT** **GOVERNMENT CODE § 8202**

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Riverside

Subscribed and sworn to (or affirmed) before me on

this 13th day of July, 2023, by
*Date* *Month* *Year*

(1) David S. Duncan

(and (2) _____),
*Name(s) of Signer(s)*

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

C. W. PHILIPPE
COMM. # 2395551
NOTARY PUBLIC · CALIFORNIA
RIVERSIDE COUNTY
COMM. EXPIRES MAR. 10, 2026

Signature _____
*Signature of Notary Public*

*Place Notary Seal and/or Stamp Above*

**OPTIONAL**

*Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.*

**Description of Attached Document**

Title or Type of Document: Accident Designated Representative Application

Document Date: 07/13/2023 Number of Pages: _____

Signer(s) Other Than Named Above: _____

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# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/13/2022)

### Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler PRxP of CA, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable) PHY55795

Physical Address 4345 E Lowell St, Stes C & D

City Ontario, State CA Zip 91761-2222

Mailing Address (if different from physical address) Same

City n/a State n/a Zip n/a

Telephone 888-505-1485 Website www.340bpharm.com (informational purposes only)

Licensing Company Email info@340bpharm.com

### Section 2: Personal Information

First Chris Middle D Last Wakefield

Alias(es, nicknames, name changes, etc.) Chris DeCecco (Maiden Name)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted] High St

City West Newton State PA Zip 15089

Telephone [redacted] Email cwakefield@340bpharm.com

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| McKeesport Senior High School | | 09/82-06/85 | |
| **Address** | **City** | **State** | **Zip** |
| 1960 Eden Park Blvd | McKeesport | PA | 15132 |
| **Diploma/Degree obtained, if any** | | | |
| Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Bradford Business School | | 02/86 - 10/86 | |
| **Address** | **City** | **State** | **Zip** |
| 125 W Station Square Dr # 129 | Pittsburgh | PA | 15219 |
| **Diploma/Degree obtained, if any** | | | |
| Associates | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 07/19 - present | [redacted] High St | West Newton | PA | 15089 |
| 09/89 - 07/19 | [redacted] 5th Ave | East McKeesport | PA | 15035 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Healthcare Ventures Group LLC and its affiliated pharmacies | | | 03/14 - Present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 1145 Broadway St, 2nd FL | | East McKeesport | PA | 15035 |
| **Phone** | **Title** | | | |
| 412-357-5163 | **3/14 to 7/17 - Executive Assistant/Pharmacy Operations<br>7/17 to Present - Manager, Chief of Staff** | | | |

Description of Duties

Oversee Pharmacy Operations Team, Contracts, Licensing, HR, and other executive managerial duties
Oversee all specialty pharmacies, contracts, licensing, HR, and other duties

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| PharmalytIQ LLC | | | 04/19 - Present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 1145 Broadway St, 2nd FL | | East McKeesport | PA | 15035 |
| **Phone** | **Title** | | | |
| 412-357-5163 | LLC Manager | | | |

Description of Duties

Attend business meetings, manage bank account, HR duties

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Sacks Family Office Trust | | | 11/17 - Present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 1193 Beechwood Blvd | | Pittsburgh | PA | 15206 |
| **Phone** | **Title** | | | |
| 412-477-7803 | Trustee | | | |

Description of Duties

Oversee companies owned by Trust, managed bank account, other trustee duties

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| 2007 JIFT Trust | | | 2/17 to Present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 1193 Beechwood Blvd | | Pittsburgh | PA | 15206 |
| **Phone** | **Title** | | | |
| 412-477-7803 | Trustee | | | |

Description of Duties

Trust owns Healthcare Ventures Group LLC and ICARE RX LLC. Oversees day to day operations of four pharmacies and performs all Trustee duties.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| SMC Direct & SMC Returns LLC | | | 02/09 - 7/17 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 143 Wagner Road | | Evans City | PA | 16033 |
| **Phone** | **Title** | | | |
| (724) 432-3502 | Office & Returns Coordinator | | | |

Description of Duties

Processed orders for rapid diagnostic testing. Processed Pharmaceutical Returns (small family owned businesses)

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Core Capital Credit LLC | | | 10/18 - Present | |
| Business Address | | City | State | Zip |
| 1145 Broadway St, 2nd FL | | East McKeesport | PA | 15035 |
| Phone | Title | | | |
| 412-357-5163 | LLC Secretary | | | |
| Description of Duties | | | | |
| Managed bank account. No active business dealings. | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Core Business Advance LLC | | | 06/18 - Present | |
| Business Address | | City | State | Zip |
| 1145 Broadway St, 2nd FL | | East McKeesport | PA | 15035 |
| Phone | Title | | | |
| 412-357-5163 | LLC Secretary | | | |
| Description of Duties | | | | |
| Managed bank account. No active business dealings. | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| GMA Hard Money LLC | | | 02/17 - | |
| Business Address | | City | State | Zip |
| 1145 Broadway St., 2nd FL | | East McKeesport | PA | 15035 |
| Phone | Title | | | |
| 412-357-5163 | LLC Secretary | | | |
| Description of Duties | | | | |
| Managed bank account, ran background checks on potential financing deals | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Corefund Capital LLC | | | 06/16 - 03/23 | |
| Business Address | | City | State | Zip |
| 1193 Beechwood Blvd | | Pittsburgh | PA | 15206 |
| Phone | Title | | | |
| 412-477-7803 | LLC Secretary | | | |
| Description of Duties | | | | |
| Managed bank account | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| GMA MCA Tracer LLC - GMA Business Credit | | | 06/16 - Present | |
| Business Address | | City | State | Zip |
| 1145 Broadway St, 2nd FL | | East McKeesport | PA | 15035 |
| Phone | Title | | | |
| 412-357-5163 | LLC Secretary | | | |
| Description of Duties | | | | |
| None - companies never operated. | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| 10485 Frankstown Road LLC | | | 06/2011 - 07/22 |
| **Business Address** | **City** | **State** | **Zip** |
| 1145 Broadway St 2nd FL | East McKeesport | PA | 15035 |
| **Phone** | **Title** | | |
| 412-357-5163 | None | | |
| **Description of Duties** | | | |
| Managed Bank account. Rental Property - Sold | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Fresh Start Capital LLC | | | 02/09 - 11/21 |
| **Business Address** | **City** | **State** | **Zip** |
| 1145 Broadway St 2nd FL | East McKeesport | PA | 15035 |
| **Phone** | **Title** | | |
| 412-357-5163 | None | | |
| **Description of Duties** | | | |
| Managed Bank account. Rental Property - Sold | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| JSK Development LLC | | | 04/16 - 03/23 |
| **Business Address** | **City** | **State** | **Zip** |
| 1145 Broadway St 2nd FL | East McKeesport | PA | 15035 |
| **Phone** | **Title** | | |
| 412-357-5163 | None | | |
| **Description of Duties** | | | |
| Managed Bank account. Rental Properties - sold | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |
| | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | ✓ | |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | ✓ | |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✓ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # 4 . Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| | | | | |
| Reason/Charge | | | | |
| | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| | | | | |
| Name of Business/Industry/Entity | | | | |
| | | | | |

**Provide explanation below:**

SEE ATTACHED LIST

Chris Wakefield
Original Signature (electronic, copies or stamps not accepted)

07/04/2023
Date

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # 5 . Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| Reason/Charge | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| Name of Business/Industry/Entity | | | | |

**Provide explanation below:**

SEE ATTACHED LIST

Chris Wakefield
Original Signature (electronic, copies or stamps not accepted)

07/04/2023
Date

CW

1712

## List of Lawsuits/Arbitration/Bankruptcies for Entities where Chris Wakefield is Officer/Director/Manager*

*** For Submission with California Out-of-State Pharmacy License Application**

| Name of Entity / Entities | Case Caption | Type of Entity | Jurisdiction | Date(s) Associated with Litigation or other Proceeding |
|---|---|---|---|---|
| Corefund Capital, LLC | Corefund Capital, LLC v. AK Singh & Sons Corp. d/b/a North Star Trucking Services, et al., Case No. 18-cv-0808 | limited liability company - alternative finance company for factoring - not related to pharmacy operations | Parker County, TX - District Court | Date of filing: July 5, 2018 (ongoing) |
| Corefund Capital, LLC | Corefund Capital, LLC v. Summit Container Corp. et al., Case No. 18-cv 0522 | limited liability company - alternative finance company for factoring - not related to pharmacy operations | Parker County, TX - District Court | Date of filing: May 3, 2018 (settled and discontinued) |
| Corefund Capital, LLC | Corefund Capital, LLC v. Aaron Jordan, et al., Case No. 096-298052-18 | limited liability company - alternative finance company for factoring - not related to pharmacy operations | Tarrant County, TX - District Court | Date of filing: Feb. 21, 2018 (settled and discontinued) |
| Hardcore Dispatch Services, LLC and Corefund Capital, LLC | Jorge Medina v. Hardcore Dispatch Services, LLC, et al., Case No. 1:19-cv-22269 | limited liability company - alternative finance company offering factoring and dispatch services - not related to pharmacy operations | U.S. District Court for Southern District of FL | Date of filing: June 3, 2019 (settled and discontinued) |
| GMA USA LLC | Anthia Hill v. Frances Gecker v. CapCall, LLC, et al., Adversary Proceeding No. 17-00066 | limited liability company - merchant cash advance - not related to pharmacy operations | U.S. Bankruptcy Court for Northern District of IL | Date of filing: March 2017 (settled and discontinued) |
| GMA USA LLC | GMA USA LLC v. Marycrest Development 1, Series LLC, Case No. 16-ch-12478 | limited liability company - hard money lending - not related to pharmacy operations | Circuit Court of Cook Co., IL (Chancery Division) | 2016 (ongoing) |

Chris Wakefield
PRINT NAME (FIRST, LAST)

Chris Wakefield
ORIGINAL SIGNATURE

07/04/2023
DATE

cw

1713

## List of Lawsuits/Arbitration/Bankruptcies for Entities where Chris Wakefield is Officer/Director/Manager*

*** For Submission with California Out-of-State Pharmacy License Application**

| Name of Entity / Entities | Case Caption | Type of Entity | Jurisdiction | Date(s) Associated with Litigation or other Proceeding |
|---|---|---|---|---|
| GMA USA LLC | GMA USA LLC v. Dream Castles, LLC, Case No. GD-18-011124 | limited liability company | Court of Common Pleas of Allegheny County, Pennsylvania | Date of filing: August 2018 (settled and discontinued) |
| JSK Development, LLC | JSK Development LLC v. Board of Property Assessment Appeals and Review of Allegheny County, BV-18-793, BV-18-795, BV-18-796 | limited liability company - holder of commercial properties - not related to pharmacy operations | Board of Viewers of the Property Assessment Appeals and Review of Allegheny County, Pennsylvania | Date of filing: March 2018 (ongoing) |
| JSK Development, LLC | JSK Development, LLC v. Robert Price, Case No. GD-19-000345 | limited liability company - holder of commercial properties - not related to pharmacy operations | Court of Common Pleas of Allegheny County, Pennsylvania | Date of filing: Jan. 9, 2019 (ongoing) |
| Healthcare Ventures Group, LLC | Healthcare Ventures Group, LLC v. Premier Pharmcy Services, Joel Yerton and Todd Weber, Case No. GD-16-023951 | limited liability company - parent company of pharmacy operations | Court of Common Pleas of Allegheny County, Pennsylvania | Date of filing: Dec. 2016 (ongoing) |
| 2007 SIFT Trust | In re: 2007 SIFT Trust Dated July 11, 2007 in the Court of Common Pleas of Allegheny County, Orphans' Court Division, at No. 02-22-05085 | trust where Chris Wakefield is the trustee | Court of Common Pleas of Allegheny County, Pennsylvania, Orphans' Court Division | 2022 - Settled and discontinued |

Chris Wakefield
PRINT NAME (FIRST, LAST)

Chris Wakefield
ORIGINAL SIGNATURE

07/04/2023
DATE

CW

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## List of Lawsuits/Arbitration/Bankruptcies for Entities where Chris Wakefield is Officer/Director/Manager*

*** For Submission with California Out-of-State Pharmacy License Application**

| Name of Entity / Entities | Case Caption | Type of Entity | Jurisdiction | Date(s) Associated with Litigation or other Proceeding |
|---|---|---|---|---|
| 2007 SIFT Trust | In re: 2007 SIFT Trust Dated July 11, 2007, Chris Wakefield, Trustee Trustee of the above-captioned 2007 SIFT Trust dated July 11, 2007, and Yasmin Sacks and Eli Sacks, Beneficiaries of SIFT, Plaintiffs, v. Yaakov (Jacob) Sacks, and Levi Goldstein, Trustee of the Sacks Family Grandchildrens Trust dated July 11, 2022, Defendants, and Allegheny County Department of Real Estate, Nominal Defendant No. GD-22-009653 | trust where Chris Wakefield is the trustee | Court of Common Pleas of Allegheny County, Pennsylvania, Civil Division | 2022 - Settled and discontinuted |
| 2007 SIFT Trust, Sacks Family Office Trust f/k/a Shim Sacks Family Legacy Trust Dated October 20, 2014, and Physician Helpers LLC | GMA, Inc. v. 2007 SIFT Trust, Sacks Family Office Trust in the United States District Court for the Western District of Pennsylvania at No. 2:22-cv-00551-CB | trusts where Chris Wakeflied is the trustee | United States District Court for the Western District of Pennsylvania | 2022 - Administratively closed |
| Corefund Capital, LLC | CoreFund Capital, LLC, Plaintiff, v. Frost Bank, a Texas State Bank, TBK Bank, SSB, Chris Wakefield, and Meir "Shim" Sacks, Defendants, and CoreFund Capital, LLC, Intervenor-Defendant, in the District Court, 45th Judicial District, Parker County, Texas, Case No. CV-22-0851 | limited liabiliy company, where second tier owner is Sacks Family Office Trust, Chris Wakefield, trustee | District Court, 45th Judicial District, Parker County, Texas | 2022 - Settled and discontinued |

Chris Wakefield
PRINT NAME (FIRST, LAST)

Chris Wakefield
ORIGINAL SIGNATURE

07/04/2023
DATE

CW

1715

## List of Lawsuits/Arbitration/Bankruptcies for Entities where Chris Wakefield is Officer/Director/Manager*

*** For Submission with California Out-of-State Pharmacy License Application**

| Name of Entity / Entities | Case Caption | Type of Entity | Jurisdiction | Date(s) Associated with Litigation or other Proceeding |
|---|---|---|---|---|
| Trustee Chris Wakefield | Trustee Chris Wakefield, Plaintiff, vs. Jacob Sacks, Jeremy Stern, Chaim Breitkopf, Levi Goldstein, and Bonnie Castillo in the District Court, 45th Judicial District, Parker County, Texas, Case No. CV-22-0851 | trusts where Chris Wakeflied is the trustee | District Court, 45th Judicial District, Parker County, Texas | 2022 - Settled and discontinued |
| Chris Wakefield, trustee of 2007 JIFT Trust, Sacks Family Office Trust and 2007 SIFT Trust | Yaakov Sacks and GMA, Inc., Plaintiffs, v. Williams, Coulson, Johnson, Lloyd, Parker & Tedesco, LLC, Defendant, and Chris Wakefield, Trustee of the 2007 JIFT Trust, and Sacks Family Office Trust (SFOT) and the 2007 SIFT Trust, Intervenor in the Court of Common Pleas of Allegheny County, Civil Division, at No. GD-22-009828 | trusts where Chris Wakeflied is the trustee | Court of Common Pleas of Allegheny County, Civil Division | 2022 - Settled and discontinued |

Chris Wakefield
PRINT NAME (FIRST, LAST)

Chris Wakefield
ORIGINAL SIGNATURE

07/04/2023
DATE

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Chris Wakefield

Print Name (First, Last)

Chris Wakefield

Original Signature (electronic, copies or stamps not accepted)

07/04/2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Pennsylvania, ss. County of Westmoreland

I, Chris Wakefield, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Chris Wakefield

**Original Signature**

07/04/2023

**Date**

Subscribed and Sworn to before me this 4 day of July 2023

Gail A. Struble

**Notary Public Signature**

Commonwealth of Pennsylvania - Notary Seal
Gail A. Struble, Notary Public
Westmoreland County
My commission expires February 11, 2027
Commission number 1162363
Member, Pennsylvania Association of Notaries

(Seal)

# 4RR

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Pharmacy Application

**Non-Refundable $500.00 Fee**

Rev (8/02/2022)

| Facility Location | Application Type (check all applicable) | Pharmacy Type (check all applicable) | Services the Pharmacy will Provide (check all applicable) |
|---|---|---|---|
| ☐ Nevada | ☒ New Pharmacy | ☒ Retail/Community | ☒ Retail/Community |
| ☒ Out-of-State | ☐ Ownership Change* | ☐ Hospital (# beds _____) | ☐ Non-sterile Compounding |
| | ☐ Location Change * | ☐ Internet | ☐ Sterile Compounding |
| | ☐ Name Change* | ☐ Nuclear | ☒ Mail-Order Service |
| | | ☐ Other: | ☐ Off-site Cognitive Services |
| | * If making a change, provide license #: | | ☐ Long Term Care |
| | | | ☐ Hospital |
| | PH_____ | | ☐ Other: |

| Days of Operation | | Ownership Type (check applicable box) |
|---|---|---|
| ☒ Monday | ☒ Friday | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12) |
| ☒ Tuesday | ☐ Saturday | ☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12) |
| ☒ Wednesday | ☐ Sunday | ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12) |
| ☒ Thursday | ☐ Holidays | ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12) |

### Section 1: General Information

Pharmacy Name: SKNV Pharmacy, LLC

Physical Address: 3155 SW 10th ST, Suite 6A

City: Deerfield Beach State: FL Zip: 33069

Mailing Address (if different from physical address): Same as physical

City: _____ State: _____ Zip: _____

Telephone: (888) 210-8111 Toll Free # (NAC 639.708, NRS 639.23286): (888) 210-8111

Fax: 754-277-4677 Contact Email: RXLICENSE@SKNV.COM

Website: _____

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Julia Tam

Supervising/Managing Pharmacist NV Pharmacist Registration #: 22016

**Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)**

| | |
|---|---|
| Name: Julia Tam | NV Pharmacist Registration #: 22016 |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |

| Section 3: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✓ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction? | | ✓ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry? | | ✓ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✓ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✓ |

**If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.**

**Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)**

| | | |
|---|---|---|
| Name: N/A | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

## Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

## Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): SKNV Pharmacy Services, LLC

Corporation/Organization Name: _____

Mailing Address: 3155 SW 10th ST, Suite 6A

City: Deerfield Beach State: FL Zip: 33442

Telephone: (888) 210-8111 Email: RXLICENSE@SKNV.COM

Contact Person Name: Maria Yeager

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

## Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

## Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

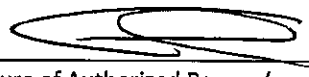
## Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

### Statement of Responsibility

1. I am the President (title) for SKNV Pharmacy, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Jonathan Fenster

Print Name of Authorized Person



Original signature of Authorized Person (copies or stamps not accepted)

05/22/2023

Date

**Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding**

**Affidavit for Pharmacy License**

I, Jonathan Fenster hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President (title) for SKNV Pharmacy, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 22 day of May, 2023

Notary Public

MARIA C YEAGER
Notary Public - State of Florida
Commission # HH 348453
My Comm. Expires Jan 22, 2027
Bonded through National Notary Assn.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jonathan Fenster, President

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

05/22/2023

Date

| Board Use Only | Date Received: 6/20/23 | Amount: 500-CK-1158 |
|---|---|---|

AC# 11785846

# STATE OF FLORIDA
# DEPARTMENT OF HEALTH
# DIVISION OF MEDICAL QUALITY ASSURANCE

| DATE | LICENSE NO. | CONTROL NO. |
|---|---|---|
| 05/16/2023 | PH 34580 | 142135 |

THE PHARMACY

NAMED BELOW HAS MET ALL REQUIREMENTS OF THE LAWS AND RULES OF THE STATE OF FLORIDA.

QUALIFICATION(S):
Community Pharmacy

Expiration Date: FEBRUARY 28, 2025
SKNV PHARMACY, LLC
3155 SOUTHWEST 10TH STREET,
SUITE 6A
DEERFIELD BEACH, FL - 33442

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
State Surgeon General

DISPLAY IF REQUIRED BY LAW

AC# 11785846

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

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THE PHARMACY

NAMED BELOW HAS MET ALL REQUIREMENTS OF THE LAWS AND RULES OF THE STATE OF FLORIDA.

Expiration Date : FEBRUARY 28, 2025

SKNV PHARMACY, LLC

QUALIFICATION(S):
Community Pharmacy

REGISTRANT SIGNATURE

## Ownership Information

**SKNV Pharmacy, LLC**, Pharmacy Owner and Operator
Business Address: 3155 SW 10th ST, Suite 6A, Deerfield Beach, FL 33442
Phone Number: (888) 210-8111
Email: RXLICENSE@SKNV.COM

**SKNV Pharmacy Services, LLC**, Sole Member of SKNV Pharmacy, LLC
Business Address: 3155 SW 10th ST, Suite 6A, Deerfield Beach, FL 33442
Phone Number: (888) 210-8111
Email: LEGAL@SKNV.COM

**Jonathan Fenster, President of SKNV Pharmacy, LLC**
Business Address: 3155 SW 10th ST, Suite 6A, Deerfield Beach, FL 33442
DOB [redacted]

**Mission:**
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

**Ron DeSantis**
Governor

**Joseph A. Ladapo, MD, PhD**
**State Surgeon General**

**Vision:** To be the **Healthiest State** in the Nation

May 16, 2023

Sknv Pharmacy, Llc
3155 Sw 10St
Suite 6A
Deerfield Beach, FL 33442

RE: License Certification for Sknv Pharmacy, Llc

To Whom It May Concern:

This is to certify the following information, maintained in the records of the Department of Health, for the above referenced Health Care Practitioner:

| | |
|---|---|
| PROFESSION: | Pharmacy |
| LICENSE NUMBER: | PH34580 |
| ORIGINAL CERTIFICATION: | 05/15/2023 |
| EXPIRATION DATE: | 02/28/2025 |
| CURRENT STATUS OF LICENSE: | CLEAR, |
| AGENCY ACTION: | No |
| LICENSE GRANTED BY: | N/A |
| OTHER CERTIFICATIONS: | Community Pharmacy |

To expedite the verification process, the above format is the standard format for all healthcare practitioners. If you have questions regarding the status of this license, please call the Customer Contact Center at (850) 488-0595, option 5.

Sincerely,

Gwendolyn B. Freeman

Gwendolyn B. Freeman
Operations and Management Consultant Manager

**Florida Department of Health**
Division of Medical Quality Assurance• Bureau of Operations
4052 Bald Cypress Way, Bin C10 • Tallahassee, FL 32399-3251
PHONE: (850) 488-0595 • FAX : (850) 245-4791

PHAB Accredited Health Department
Public Health Accreditation Board

# STATE OF FLORIDA
# DEPARTMENT OF HEALTH
# INVESTIGATIVE SERVICES
## INV355 - Community Pharmacy (New Business / Change of Owner)

www.FloridaHealth.gov

File # 29229
Insp # 191869

| NAME | PERMIT NUMBER | DATE OF INSPECTION | |
|---|---|---|---|
| SKNV Pharmacy, LLC | | 05/12/2023 | |
| **DOING BUSINESS AS** | | | |
| **STREET ADDRESS**<br>3155 Southwest 10th Street, Suite 6A | | **TELEPHONE #**<br>888-210-8111 | **EXT** |
| **CITY**<br>DEERFIELD BEACH | **COUNTY**<br>BROWARD | **STATE/ZIP**<br>FL/33442 | |

**Additional Information**

**Business Operation Hours**

| | |
|---|---|
| Sunday N | M-T-W-TH-F N |
| Monday Y | Monday Hours 9:00 am to 5:00 pm |
| Tuesday Y | Tuesday Hours 9:00 am to 5:00 pm |
| Wednesday Y | Wednesday Hours 9:00 am to 5:00 pm |
| Thursday Y | Thursday Hours 9:00 am to 5:00 pm |
| Friday Y | Friday Hours 9:00 am to 5:00 pm |
| Saturday N | |

**Registered Pharmacist / Intern / Tech**

| | |
|---|---|
| License # PS58606 | Licensee Name Julia Tam |
| License Type Registered Pharmacists | |

**ACS Manager**

| | |
|---|---|
| | |

**Optional Information**

| | |
|---|---|
| | |

**Basic License Data - PSD**

| | |
|---|---|
| DEA Reg # N/A | |

**License Relations**

**Pharmacy Affiliate**

| | |
|---|---|
| TAM, JULIA | License # 58606 |

**RX DPT MGR/COR/POR**

| | |
|---|---|
| TAM, JULIA | License # 58606 |

## INV355 - Community Pharmacy (New Business / Change of Owner)

**COMMUNITY REQUIREMENTS GENERAL SECTION**

| | |
|---|---|
| Rx Department is open for a minimum of 20 hours per week and signage stating the hours the pharmacy department is open. [64B16-28.1081, F.A.C.] | Yes |
| Patient Consultation Area sign is posted. [64B16-28.1035, F.A.C] | Yes |
| Private Consultation Area available. [64B16-28.1035, F.A.C] | Yes |
| Generic equivalent sign is posted. [465.025(7), F.S] | Yes |
| Prescription department is clean and safe, has a sink with running water convenient to the prescription department, and references and equipment necessary for the practice of pharmacy. [64B16-28.102 F.A.C.] | Yes |
| Pharmacy has a designated Prescription Department manager with a current and active Florida license. [465.018, F.S.]<br>*PDM Julia Tam Lic. #PS58606* | Yes |
| Written policy and procedure manual regarding the number of technician positions and their utilization. [64B16 -27.410(2)(a) F.A.C.] | Yes |
| Continuous Quality Improvement Program described in Policy and Procedure manual [64B16-27.300 F.A.C.] [ 766.101(1)(a)(l) F.S.] | Yes |

# INV355 - Community Pharmacy (New Business / Change of Owner)

**Insp # 191869**

**SKNV Pharmacy, LLC**

**File # 29229**

| | |
|---|---|
| Policy and Procedure to prevent the fraudulent dispensing or controlled substances. [465.022 (4) F.S] | Yes |
| Prescription Department is securable from unauthorized access. [64B16-28.109 F.A.C.] | Yes |
| All medications to be purchased from a Florida licensed wholesaler [499-F.S.]<br>*Wholesaler: Will be MEDLINE* | Yes |
| The following rules have been reviewed with the applicant: 64B16-30.003, F.A.C. (Citations), 64B16-28.140(4) F.A.C. (Compounding Records), 64B16-28.1081, F.A.C. (Regulation of Daily Operating Hours; Commencement of Operation-s), 64B16-28.202, F.A.C (Closing of a Pharmacy) | Yes |

**Pharmacy Ships Medicinal Drugs to Patients [ 64B16-28.10801, F.A.C]**

| | |
|---|---|
| Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent. | Yes |
| Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs. | Yes |

**Automated Pharmacy System [465.0235, F.S.]**

| | |
|---|---|
| Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years. | |

## Remarks:

This is a new Pharmacy;

Inspection completed with PDM Julia Tam Lic. #PS58606

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

MENDEZ, JUAN CARLOS

JCM

Date:5/12/2023

Representative:

Julia Tam

Date:5/12/2023

# Delaware

The First State



*I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SKNV PHARMACY, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FOURTH DAY OF APRIL, A.D. 2023.*

*AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "SKNV PHARMACY, LLC" WAS FORMED ON THE NINETEENTH DAY OF JANUARY, A.D. 2023.*

Jeffrey W. Bullock, Secretary of State

7248863 8300

SR# 20231292614

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203078586

Date: 04-04-23

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

### Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: SKNV Pharmacy, LLC

Pharmacy/Wholesaler License # (if applicable): Pending

Physical Address: 3155 SW 10th ST, Suite 6A

City: Deerfield Beach State: FL Zip: 33442

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 888-210-8111 Website:

Licensing Company Email: RXLICENSE@SKNV.COM

### Section 2: Personal Information

First: Julia Middle: Last: Tam

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: 3155 SW 10th ST, Suite 6A

City: Deerfield Beach State: FL Zip: 33442

Telephone: 888-210-8111 Email: JTAM@SKNV.COM

Are you a citizen of the United States? ■ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Nova Southeastern University | | 2014-2018 | |
| **Address** | **City** | **State** | **Zip** |
| 3300 S University Drive | Fort Lauderdale | FL | 33328 |
| Diploma/Degree obtained, if any | | | |
| Doctor of Pharmacy | | | |
| School Name | | From - To (MM/YY – MM/YY) | |
| Nova Southeastern University | | 2011-2015 | |
| **Address** | **City** | **State** | **Zip** |
| 3300 S University Drive | Fort Lauderdale | FL | 33328 |
| Diploma/Degree obtained, if any | | | |
| Bachelor of Science in Biology | | | |
| School Name | | From - To (MM/YY – MM/YY) | |
| Saint Thomas Aquinas High School | | | |
| **Address** | **City** | **State** | **Zip** |
| 2801 SW 12th St | Ft Lauderdale | FL | 33312 |
| Diploma/Degree obtained, if any | | | |
| High School Diploma | | | |
| School Name | | From - To (MM/YY – MM/YY) | |
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |
| School Name | | From - To (MM/YY – MM/YY | |
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 08/22 - Present | [redacted] NE 15 Ave | Ft. Lauderdale | FL | 33305 |
| 05/15 - 08/22 | [redacted] Matador Lane | Davie | FL | 33324 |
| 01/96 - 05/15 | [redacted] Lake Park Cir N | Davie | FL | 33328 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| SKNV Pharmacy, LLC | | | 04/23 - Present | |
| **Business Address** | **City** | | **State** | **Zip** |
| 3155 SW 10th Street, Suite 6A | Deerfield Beach | | FL | 33442 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 888-210-8111 | Pharmacist in Charge | | 320 | |
| **Description of Duties** | | | | |
| Created workflow management and supervised day to day operations. Maintained pharmacy compliance with all state and federal laws for additional pharmacy state licensure. | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Aids Healthcare Foundation | | | 05/22 -05/23 | |
| **Business Address** | **City** | | **State** | **Zip** |
| 700 SE 3rd Ave | Fort Lauderdale | | FL | 33316 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 954 767 0273 | Staff Pharmacist | | 2080 | |
| **Description of Duties** | | | | |
| Provide HIV/AIDS medical care to patients, accurately dispensing prescription orders, and maintaining confidential patient information. | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| National Treatment Delivery and Care LLC | | | 10/20 - 03/23 | |
| **Business Address** | **City** | | **State** | **Zip** |
| 710 South Military Trail Suite 710 | Deerfield Beach | | FL | 33442 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 877 791 2806 | Pharmacist in Charge | | 4,507 | |
| **Description of Duties** | | | | |
| Created workflow management and supervised day to day operations. Maintained pharmacy compliance with all state and federal laws for additional pharmacy state licensure. | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| ProCare Pharmacy Care LLC | | | 07/18 - 01/21 | |
| **Business Address** | **City** | | **State** | **Zip** |
| 2650 SW 145th Ave | Miramar | | FL | 33027 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 800 662 0586 | Pharmacist in Charge | | 5,025 | |
| **Description of Duties** | | | | |
| Supervised day to day operations. Managed staff training related to their job description. | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Walgreens Pharmacy | | | 08/13 - 10/22 | |
| **Business Address** | **City** | | **State** | **Zip** |
| 8790 W McNab Rd | Tamarac | | FL | 33321 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 954 726 6008 | Technician to Staff Pharmacist | | 7,488 | |
| **Description of Duties** | | | | |
| Provide pharmaceutical care to customers, including processing and accurately dispensing prescription orders, counseling customers regarding health care and prescription medication needs, maintaining confidential information. | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✓ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✓ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✓ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # N/A. **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

05/30/23
Date

I, Julia Tam, **certify that as the designated representative for**

SKNV Pharmacy, LLC,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. JT I am at least 21 years of age;
3. JT I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JT I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JT I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JT I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JT I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Julia Tam
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

05/30/23
Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Julia Tam
Print Name (First, Last)

Julia Tam
Original Signature (electronic, copies or stamps not accepted)

05/30/2023
Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Florida, ss. County of Broward

I, Julia Tam, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Julia Tam
**Original Signature**

05/30/2023
**Date**

Subscribed and Sworn to before me this 30th day of May.

**Notary Public Signature**

MARIA C YEAGER
Notary Public - State of Florida
Commission # HH 348453
My Comm. Expires Jan 22, 2027
Bonded through National Notary Assn.

**(Seal)**

# 4SS

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Pharmacy Application
## Non-Refundable $500.00 Fee

Rev (8/02/2022)

| Facility Location | Application Type (check all applicable) | Pharmacy Type (check all applicable) | Services the Pharmacy will Provide (check all applicable) |
|---|---|---|---|
| ☐ Nevada | ☐ New Pharmacy | ■ Retail/Community | ■ Retail/Community |
| ■ Out-of-State | ■ Ownership Change* | ☐ Hospital (# beds _____) | ☐ Non-sterile Compounding |
| | ☐ Location Change * | ☐ Internet | ☐ Sterile Compounding |
| | ☐ Name Change* | ☐ Nuclear | ■ Mail-Order Service |
| | | ☐ Other: | ☐ Off-site Cognitive Services |
| | * If making a change, provide license #: | | ☐ Long Term Care |
| | | | ☐ Hospital |
| | PH 04135 | | ☐ Other: |

| Days of Operation | | Ownership Type (check applicable box) |
|---|---|---|
| ■ Monday | ■ Friday | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12) |
| ■ Tuesday | ☐ Saturday | ■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12) |
| ■ Wednesday | ☐ Sunday | ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12) |
| ■ Thursday | ☐ Holidays | ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12) |

### Section 1: General Information

Pharmacy Name: URGENTMEDRX, LLC

Physical Address: 6971 N FEDERAL HWY, SUITE 203

City: BOCA RATON State: FLORIDA Zip: 33487

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 888-536-9963 Toll Free # (NAC 639.708, NRS 639.23286): 888-536-9963

Fax: 844-267-9645 Contact Email: RPH@URGENTMEDRX.COM

Website: URGENTMEDRX.COM

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): GRACE CARPENTER

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23802

**Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy. (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)**

| | |
|---|---|
| Name: GRACE CARPENTER | NV Pharmacist Registration #: |
| Name: DAVID STEINBERG | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |

| Section 3: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✓ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction? | | ✓ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry? | | ✓ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✓ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✓ |

**If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.**

**Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)**

| | | |
|---|---|---|
| Name: NA | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

**Section 5: Publicly Traded Corporation**

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 6: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: FLORIDA

Parent Company (if any): _____

Corporation/Organization Name: URGENTMEDRX, LLC

Mailing Address: 6971 N FEDERAL HWY SUITE 203

City: BOCA RATON State: FLORIDA Zip: 33478

Telephone: 888-536-9963 Email: RPH@URGENTMEDRX.COM

Contact Person Name: GRACE CARPENTER

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

**Section 7: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 8: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

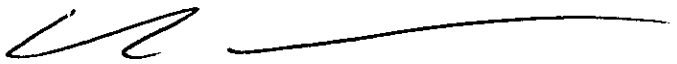
**Section 9: Statement of Responsibility- MUST BE COMPLETED by an Authorized Person (NAC 639.945)**

## Statement of Responsibility

1. I am the OWNER (title) for URGENTMEDRX, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

BRYAN PLONSKY

Print Name of Authorized Person



Original signature of Authorized Person (copies or stamps not accepted)

06/28/2023

Date

**Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding**

## Affidavit for Pharmacy License

I, GRACE CARPENTER hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the PIC (title) for URGENTMEDRX, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 24 day of June, 2023

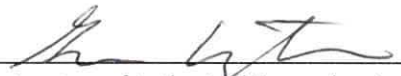
Notary Public

BRYAN PLONSKY
Notary Public - State of Florida
Commission # HH 123210
My Comm. Expires May 18, 2025
Bonded through National Notary Assn.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

GRACE CARPENTER

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

06/28/2023

Date

| Board Use Only | Date Received: 7/3/23 | Amount: 500-CK-2172 |
|---|---|---|

URGENTMEDRX

6971 N. Federal Highway Suite 203
Boca Raton, FL 33487
FEIN #83-1124011

Bryan Plonksy 50%
SSN: [redacted]
DOB: [redacted]
Email: Bryan@seniorinformationcenters.com
Home Address: [redacted] Parkside Circle S, Boca Raton, FL 33486
Phone#: [redacted]
Business #: 561-998-6039

Stephen Wolfe 50%
SSN: [redacted]
DOB: [redacted]
Email Stephen@seniorinformationcenters.com
Home Address: [redacted] Cadena Dr, Boca Raton, FL 33496
Phone#: [redacted]
Business#: 561-998-6039

# State of Florida
## Department of State

I certify from the records of this office that URGENTMEDRX LLC is a limited liability company organized under the laws of the State of Florida, filed on June 15, 2018.

The document number of this limited liability company is L18000148509.

I further certify that said limited liability company has paid all fees due this office through December 31, 2023, that its most recent annual report was filed on January 27, 2023, and that its status is active.

*Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the First day of June, 2023 •*

GREAT SEAL OF THE STATE OF FLORIDA
IN GOD WE TRUST

*Secretary of State*

**Tracking Number: 5998408740CU**

**To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.**

**https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication**

# STATE OF FLORIDA
# DEPARTMENT OF HEALTH
# INVESTIGATIVE SERVICES
## INV359 - Community Requirements

www.FloridaHealth.gov

File # 25668
Insp # 175991

| NAME | PERMIT NUMBER | DATE OF INSPECTION |
|---|---|---|
| URGENTMEDRX, LLC | 31689 | 02/02/2023 |
| **DOING BUSINESS AS** | | |
| **STREET ADDRESS**<br>6971 N. FEDERAL HIGHWAY SUITE 203 | **TELEPHONE #**<br>561-826-9563 | **EXT** |
| **CITY**<br>BOCA RATON | **COUNTY**<br>PALM BEACH | **STATE/ZIP**<br>FL/33487 |

**Additional Information**

**Business Operation Hours**

| | |
|---|---|
| M-T-W-TH-F Y | Weekly Hours 9:00 am to 5:00 pm |
| Monday N | Monday Hours |
| Tuesday N | Tuesday Hours |
| Wednesday N | Wednesday Hours |
| Thursday N | Thursday Hours |
| Friday N | Friday Hours |
| Saturday N | Saturday Hours |
| Sunday N | Sunday Hours |

**Registered Pharmacist / Intern / Tech**

| | |
|---|---|
| License # 54676 | Licensee Name David Levi Steinberg |
| License Type Registered Pharmacists | |

**ACS Manager**

| | |
|---|---|
| | |

**Optional Information**

| | |
|---|---|
| | |

**Basic License Data - PSD**

| | |
|---|---|
| DEA Reg # FU8024983 | |

**License Relations**

**Pharmacy Affiliate**

| | |
|---|---|
| PLONSKY, BRYAN MICHAEL | License # |
| STEINBERG, DAVID LEVI | License # 54676 |
| WOLFE, STEPHEN | License # |

**RX DPT MGR/COR/POR**

| | |
|---|---|
| CARPENTER, GRACE MARIE | License # 43300 |

## INV 359 - Community Requirements

**Signage Requirements Section**

| | |
|---|---|
| Signage stating the hours the pharmacy department is open. [64B16-28.1081 (2) F.A.C.] | Yes |
| A sign with bold letters not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons stating, "Prescription Department Closed". [64B16-28.109 F.A.C.] | Yes |
| Patient Consultation Area sign is posted. [64B16-30.003, F.A.C] | Yes |

**Community Requirements General Section**

| | |
|---|---|
| Expired medications removed from the shelves. [64B16-28.110 F.A.C.]; [64B16-28.1191 F.A.C.] | Yes |

# INV359 - Community Requirements

Insp # 175991 | URGENTMEDRX, LLC | File # 25668

| | |
|---|---|
| Rx Department is open for a minimum of 20 hours per week. [64B16-28.1081 (1) F.A.C.] | Yes |
| All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c) F.S.]; [21CFR1306.05] | Yes |
| Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)]; [64B16-28.140(3)(d) & F.A.C]<br>*Daily logs observed, in compliance.* | Yes |
| Prescription department has current copy of laws and rules, references and equipment necessary to the professional practice of pharmacy. [64B16-28.102 F.A.C.] | Yes |
| Pharmacy technicians and interns properly identified and supervised [64B16-27.100 (2) F.A.C.]; [64B16-27.4001 F.A.C.]; [64B16-27.410 F.A.C.]; [64B16-27.420 F.A.C.].<br>*No technicians employed.* | N/A |
| Legend drugs properly stored. [64B16-28.118 F.A.C.]; [64B16-28.120 F.A.C.] | Yes |
| Documentation of destruction of controlled substances. [64B16-28.303, F.A.C.]<br>*Outdate RX* | Yes |
| Generic equivalent sign is posted. [465.025(7), F.S] | Yes |

**Additional Community Requirements**

| | |
|---|---|
| Prescription department is clean and safe, has a sink with running water convenient to the prescription department. [64B16-28.102 F.A.C.] | Yes |
| Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.] | Yes |
| When a pharmacist is not on duty, the prescription department is securely locked, and no other personnel remain in the department. [64B16-28.109 F.A.C.] | Yes |
| Written policy and procedure manual regarding the number of technician positions and their utilization. [64B16-27.410(2) (a), F.A.C.] | Yes |
| Documentation signed by Pharmacy technician acknowledging review of the Policy and Procedure manual within 90 days of hire. [64B16-27.410(2) (b), F.A.C.]<br>*No technicians employed.* | N/A |
| Documentation that Pharmacy technician has been trained in the established job description. [64B16-27.410(2)(c), F.A.C.]<br>*No technicians employed.* | N/A |
| Pharmacy licenses are current. [465.015(1)(a) F.S.] | Yes |
| Private consultation area available [6416-28.1035 F.A.C.] | Yes |
| Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.] | Yes |
| Medication properly labeled. [499 F.S.]; [64B16-28.108 F.A.C.]; [893.04(1)(e) F.S.] [21CFR1306.24]; [21CFR1306.14] | Yes |
| Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and summarization of Quality -Related Events which have been reviewed by the CQI committee quarterly are available for inspection. [64B16-27.300 F.A.C.]; [766.101(1)(a)(l) F.S.]<br>*CQI's observed, in compliance.* | Yes |
| Policy and Procedure available and implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.] | Yes |
| Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.] | Yes |
| Written prescriptions for controlled substances are on counterfeit-proof pads from Department-approved vendors. [893.065 F.S.]; [456.42(2) F.S.] | Yes |
| Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a) F.S.]; [21CFR1304.11]<br>*January 2023, COB.* | Yes |
| DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2) F.S.]; 21CFR 1305.13(e)]; [21CFR1305.22(g)]<br>*In compliance.* | Yes |
| Controlled substance records and Rx information in computer system are retrievable. [21CFR1304.04]; [465.022(12) (a) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.] | Yes |
| Controlled substance records are maintained for 4 years [465.022(12) (b) F.S.] [64B16-28.140 F.A.C.] | Yes |
| Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]<br>*None to report.* | N/A |
| Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b) F.S.]; [465.022(11) (b) F.A.C.]<br>*None to report.* | N/A |
| Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4) (3)(a), F.S.] | Yes |
| Compounding records properly maintained. [64B16-28.140(4), F.A.C.]<br>*No compounding conducted at this establishment.* | N/A |
| The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005 F.S.] [61N-1.012 F.A.C.] | Yes |
| Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005 (14) F.S.]<br>*McKesson* | Yes |
| Administration begins not later than 1 hour following start of immediate use CSPs preparation. [64B16-27.797 F.A.C.] | N/A |
| Facility engaged in non-sterile office use compounding for human use is registered with FDA as an outsourcing facility [F.A.C 64B16-27.700(3)(g)] | N/A |
| Signage indicating that any patient receiving testing, screening, or treatment services is advised to seek followup care from his or her primary care physician. [465.1895 (9) F.S.] | N/A |
| Pharmacist has a written collaborative practice agreement. [465.1865, F.S.] | N/A |
| Human Trafficking signage is posted in a conspicuous place accessible to employees that is at least 11 inches by 15 inches in size, printed in a clearly legible font and in at least a 32-point type which gives instructions in English and Spanish on how to report to the National Human Trafficking Resource Center. [456.0341, F.S] | Yes |

**Pharmacy Ships Medicinal Drugs to Patients [ 64B16-28.10801, F.A.C]**

# INV359 - Community Requirements

Insp # 175991 | URGENTMEDRX, LLC | File # 25668

| | |
|---|---|
| Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent. | Yes |
| Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs. | Yes |

**Pharmacy engages in Centralized Prescription Filling? [64B16-28.450, F.A.C.]**

| | |
|---|---|
| Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy. | |
| Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions. | |
| The originating pharmacy is identified with pharmacy name and address on the prescription container label. | |
| The central fill pharmacy is identified by name and address or a by a code available at the originating pharmacy. | |
| If a controlled substance, the word "central fill" appears on the face of the original prescription. | |
| The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy's employee accepting delivery. | |

**Automated Pharmacy System [465.0235, F.S.]**

| | |
|---|---|
| Pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling. | |
| Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years. | |

**Internet Pharmacy**

| | |
|---|---|
| A toll-free telephone number is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. [465.0197 (3)(e), F.S.] | |
| Toll free number is disclosed on the label affixed to each container of dispensed medicinal drugs. [465.0197 (3)(e), F.S.] | |
| Documentation of a valid, unexpired pharmacy license, permit or registration in the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed. [465.0197(3)(a) F.S] | |

## Remarks:

Routine inspection conducted by Inspector Asaro on 2/2/23 along with Grace Carpenter, PDM.
No technicians employed, no compounding conducted. Facility is in compliance.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

ASARO, JENNIFER

Date:2/2/2023

Representative:

Grace Carpenter

Date:2/2/2023



AC# 1174085

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

| DATE | LICENSE NO. | CONTROL NO. |
|---|---|---|
| 02/11/2023 | PH 31669 | 138796 |

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA

Expiration Date: FEBRUARY 28, 2025
URGENTMEDRX, LLC
6971 N. FEDERAL HIGHWAY
SUITE 203
BOCA RATON, FL 33487

QUALIFICATION(S)
Schedule II & III
Community Pharmacy

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
State Surgeon General

DISPLAY IF REQUIRED BY LAW

Florida HEALTH Department of Health

# URGENTMEDRX, LLC

## License Number: PH31689

*Data As Of 5/24/2023*

| | | |
|---|---|---|
| **Profession** | Pharmacy | |
| **License** | PH31689 | |
| **License Status** | CLEAR/ | |
| **Qualifications** | Schedule II & III | Community Pharmacy |
| **License Expiration Date** | 2/28/2025 | |
| **License Original Issue Date** | 10/05/2018 | |
| **Address of Record** | 6971 N. FEDERAL HIGHWAY<br>SUITE 203<br>BOCA RATON, FL 33487 | |
| **Discipline on File** | No | |
| **Public Complaint** | No | |

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

1752

URGENTMEDRX, LLC
6971 N FEDERAL HWY STE 203
BOCA RATON, FL 33487-5703

1: 4
372/525

10003646. 2/001431-1/1-0

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| FU8024983 | 05-31-2024 | $888 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N, 3,3N,4,5 | RETAIL PHARMACY | 04-02-2021 |

*URGENTMEDRX, LLC*
*6971 N FEDERAL HWY STE 203*
*BOCA RATON, FL 33487-1648*

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

**THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.**


**CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE**
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| FU8024983 | 05-31-2024 | $888 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N, 3,3N,4,5 | RETAIL PHARMACY | 04-02-2021 |

URGENTMEDRX, LLC
6971 N FEDERAL HWY STE 203
BOCA RATON, FL 33487-1648

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.


Form DEA-223 (9/2016)

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

**Section 1: Pharmacy/Wholesaler Information**

Name of Pharmacy/Wholesaler URGENTMEDRX,LLC

Pharmacy/Wholesaler License # (if applicable) PH04135

Physical Address 6971 N FEDERAL HWY, SUITE 203

City BOCA RATON State FL Zip 33487

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 888-536-9963 Website URGENTMEDRX.COM

Licensing Company Email _____

**Section 2: Personal Information**

First GRACE Middle MARIE Last CARPENTER

Alias(es, nicknames, name changes, etc.) GRACE GARZA, GRACE MCNARON

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address 6971 N FEDERAL HWY, SUITE 203

City BOCA RATON State FL Zip 33487

Telephone 888-536-9963 Email RPH@URGENTMEDRX.COM

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| NOVA HIGH SCHOOL | | 1994-1997 | |
| **Address** | **City** | **State** | **Zip** |
| 3600 COLLEGE AVE | DAVIE | FL | 33314 |
| **Diploma/Degree obtained, if any** | | | |
| HIGH SCHOOL DIPLOMA | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| UNIVERSITY OF MIAMI | | 1997-1999 | |
| **Address** | **City** | **State** | **Zip** |
| 1320 SOUTH DIXIE HIGHWAY | CORAL GABLES | FL | 33146 |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| NOVA SOUTH EASTERN UNIVERSITY-UNDERGRAD | | 1999-2001 | |
| **Address** | **City** | **State** | **Zip** |
| 3300 S UNIVERSITY DR | FT LAUDERDALE | FL | 33328 |
| **Diploma/Degree obtained, if any** | | | |
| BACHELORS SCIENCE | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| NOVA SOUTH EASTERN UNIVERSITY- GRAD | | 2001-2007 | |
| **Address** | **City** | **State** | **Zip** |
| 3300 S UNIVERSITY DR | FT LAUDERDALE | FL | 33328 |
| **Diploma/Degree obtained, if any** | | | |
| PHARMD | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 2008-PRESENT | [redacted] NW 57TH ST | BOCA RATON | FL | 33076 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| WALGREENS | | | 200-2014 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 14901 NW 79TH CT | | CORAL SPRINGS | FL | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | FLOATER RPH | | 30-40 weekly | |

Description of Duties

Reviewing prescriptions, organizing the pharmacy, delivering and labeling medications, and providing information and advice to patients. Ensuring safe medication use, monitor patient history, and stay updated on advancements in meds

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| CVS | | | 2015-2021 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 5044 FOREST HILL BLVD | | WEST PALM BEACH | FL | 33415 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 561-967-9118 | FLOATER RPH | | 30-40 weekly | |

Description of Duties

Reviewing prescriptions, organizing the pharmacy, delivering and labeling medications, and providing information and advice to patients. Ensuring safe medication use, monitor patient history, and stay updated on advancements in meds

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| WINN DIXIE | | | 2021-2022 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 1150 NW 54TH ST | | MIAMI | FL | 33076 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 305-757--0696 | STAFF PHARMACIST | | 40 weekly | |

Description of Duties

Reviewing prescriptions, organizing the pharmacy, delivering and labeling medications, and providing information and advice to patients. Ensuring safe medication use, monitor patient history, and stay updated on advancements in meds

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| URGENTMEDRX, LLC | | | 2022-PRESENT | |
| **Business Address** | | **City** | **State** | **Zip** |
| 6971 N FEDERAL HWY SUITE 203 | | BOCA RATON | FL | 33487 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 888-536-9936 | PIC | | 32 weekly | |

Description of Duties

Reviewing prescriptions, organizing the pharmacy, delivering and labeling medications, and providing information and advice to patients. Ensuring safe medication use, monitor patient history, and stay updated on advancements in meds

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |

Description of Duties

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✓ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✓ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✓ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

06/25/2023
Date

I, GRACE CARPENTER, **certify that as the designated representative for**

URGENTMEDRX, LLC,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. GC I am at least 21 years of age;
3. GC I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. GC I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. GC I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. GC I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. GC I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

GRACE CARPENTER

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/28/2023

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Grace Carpenter

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/28/2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Florida, ss. County of Polk Beach

I, Grace Carpenter, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

6/28/23

**Date**

Subscribed and Sworn to before me this 27 day of June 2023.

**Notary Public Signature**

BRYAN PLONSKY
Notary Public - State of Florida
Commission # HH 123210
My Comm. Expires May 18, 2025
Bonded through National Notary Assn.

**(Seal)**

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/18/2023)

### Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site URGENTMEDRX, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH04135

Physical Address 6971 N FEDERAL HWY SUITE 203

City BOCA RATON State FL Zip 33487

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 888-536-9967 Website URGENTMEDRX.COM

Licensing Company Email RPH@URGENTMEDRX.COM

### Section 2: Personal Information

First STEPHEN Middle _____ Last WOLFE

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]CADENA DR

City BOCA RATON State FL Zip 33496

Telephone [redacted] Email STEPHEN@SENIORINFORMATIONCENTERS.COM

Are you a citizen of the United States? ■ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✔ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Pennsylvania State University - Penn State | | 1989 – 1993 | |
| **Address** | **City** | **State** | **Zip** |
| State College PA | | PA | |
| **Diploma/Degree obtained, if any** | | | |
| B.A. Admin. of Justice | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Henderson High School | | | |
| **Address** | **City** | **State** | **Zip** |
| | West Chester | PA | |
| **Diploma/Degree obtained, if any** | | | |
| High school diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 2017 – 2023 | [redacted] Cadena Dr. | Boca Raton | FL | 33496 |
| 2015 - 2017 | [redacted] NW 53rd St | Boca Raton | FL | 33496 |
| 2007 – 2015 | [redacted] Rosecrest Terr | Delray Bch FL | FL | 33446 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Trusted Home Care Services | | | 2013 – 2023 | |
| Business Address | City | | State | Zip |
| 6971 N Federal Hwy Ste 202 | Boca Raton | | FL | 33487 |
| Phone | Title | | | |
| 561 9986039 | CEO | | | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | City | | State | Zip |
| | | | | |
| Phone | Title | | | |
| | | | | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | City | | State | Zip |
| | | | | |
| Phone | Title | | | |
| | | | | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | City | | State | Zip |
| | | | | |
| Phone | Title | | | |
| | | | | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| Business Address | City | | State | Zip |
| | | | | |
| Phone | Title | | | |
| | | | | |
| Description of Duties | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

06/28/2023
Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

STEPHEN WOLFE

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/28/2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Florida, ss. County of Palm Beach.

I, Stephen Wolfe, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

6/28/23

**Date**

Subscribed and Sworn to before me this 28 day of June, 23.

**Notary Public Signature**

BRYAN PLONSKY
Notary Public - State of Florida
Commission # HH 123210
My Comm. Expires May 18, 2025
Bonded through National Notary Assn.

**(Seal)**

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/18/2023)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site URGENTMEDRX

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH04135

Physical Address 6971 N FEDERAL HWY SUITE 203

City BOCA RATON State FL Zip 33478

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 888-536-9963 Website URGENTMEDRX.COM

Licensing Company Email RPH@URGENTMEDRX.COM

**Section 2: Personal Information**

First BRYAN Middle _____ Last PLONSKY

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] PARKSIDE CIRCLE S

City BOCA RATON State FL Zip 33486

Telephone [redacted] Email BRYAN@SENIORINFORMATIONCENTERS.COM

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Florida Atlantic University | | 08/91-05/93 | |
| Address | City | State | Zip |
| | Boca Raton | FL | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| College of Boca Raton | | 08/89-05/91 | |
| Address | City | State | Zip |
| | Boca Raton | FL | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Henderson High School | | 1985-1989 | |
| Address | City | State | Zip |
| | West Chester | PA | 19380 |
| Diploma/Degree obtained, if any | | | |
| Degree | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 09/06-Current | [redacted] Parkside Circle S | Boca Raton | FL | 33486 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Trusted Home Care Services | | | 06/13 to Current |
| **Business Address** | **City** | **State** | **Zip** |
| 1200 S. Rogers Circle #4 | Boca Raton | FL | 33487 |
| **Phone** | **Title** | | |
| 561-998-6039 | CFO | | |
| **Description of Duties** | | | |
| All Financial duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |
| | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✓ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✓ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✓ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✓ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

06/28/2023

Original Signature (electronic, copies or stamps not accepted) — Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

BRYAN PLONSKY

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/28/2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Florida, ss. County of Polk

I, Bryan Plonsky, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

6/28/23

**Date**

Subscribed and Sworn to before me this 28 day of 6/2023.

**Notary Public Signature**

STEPHEN WOLFE
Notary Public - State of Florida
Commission # HH 276398
My Comm. Expires Jun 14, 2026
Bonded through National Notary Assn.

**(Seal)**

# 4TT

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Ambulatory Surgical Center (ASC) and Recovery Center (RC) Application

**Non-Refundable $500.00 Fee**

Rev (09/02/2021)

**Type of Facility**

- ☒ Ambulatory Surgical Center (ASC)
- ☐ Recovery Center (RC)

| Type of Application (check applicable box) | | Ownership Type (check applicable box) |
|---|---|---|
| ☐ New ASC/RC | * If making a change, provide current license number: | ☐ Publicly Traded (complete sections 1, 2, 3, 7, 8, 9) |
| ☒ Ownership Change* | | ☒ Non-Publicly Traded (complete sections 1, 2, 4, 7, 8, 9) |
| ☐ Location Change * | ASC02435 | ☐ Partnership (complete sections 1, 2, 5, 7, 8, 9) |
| ☐ Name Change* | | ☐ Sole Owner (complete sections 1, 2, 6, 7, 8, 9) |

**Section 1: General Information**

ASC/RC Name: Surgery Center of Reno, LLC

Physical Address: 343 Elm Street, Suite 100

City: Reno State: NV Zip: 89503

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 775-336-6900 Fax: 775-336-6910

Contact Email: landersen@surgeryreno.com Website surgerycenterofreno.com

Nevada Business License # NV20051657412

Employed/Contracted Pharmacist Name: Mary Greer NV Pharmacist License #: 10687

Medical Director Name: Daniel Sorensen, M.D.

**Days of Operation**

| ☒ Monday | ☒ Tuesday | ☒ Wednesday | ☒ Thursday | ☒ Friday | ☐ Saturday | ☐ Sunday |
|---|---|---|---|---|---|---|

| Section 2: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✓ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction? | | ✓ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry? | | ✓ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✓ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✓ |

**If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.**

**Section 3: Publicly Traded Corporation**

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 4: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: Nevada

Parent Company (if any): _____

Corporation/Organization Name: Surgery Center of Reno, LLC

Mailing Address: 343 Elm Street, Suite 100

City: Reno State: NV Zip: 89503

Telephone: 775-336-6900 Email: landersen@surgeryreno.com

Contact Person Name: Liz Andersen

Does the number of members or stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ■ No

**Section 5: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 6: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

**Section 7: Employed/Contracted Pharmacist (MUST BE COMPLETED BY the Employed/Contracted Pharmacist)**

Pharmacist Name: Mary Greer NV Pharmacist License #: 10687

**As the employed/contracted pharmacist, for (ASC/RC Name):** Surgery Center of Reno, LLC :

I understand that I am responsible for establishing policies and procedures which (NAC 639.4996):

a) Are consistent with the policies and procedures developed pursuant to NAC 639.447;
b) Require to maintain records in accordance with the provisions of NAC 639.485 and 639.485;
c) Address the purchase, storage, maintenance of records and dispensing of drugs and investigational drugs;
d) Require maintenance of a perpetual inventory of all controlled substances;
e) Prescribe the procedure for quarantining and destroying drugs and investigational drugs that are expired, adulterated, mislabeled or otherwise unsafe for human use;
f) Require the storage of drugs and investigational drugs in accordance with the specifications of the manufacturer;
g) Ensure that the ASC and RC dispenses drugs and investigational drugs pursuant to chart orders and in accordance with applicable state and federal laws; and
h) Ensure that all compounding is
    a. Performed by a registered pharmacist in accordance with the provisions of NRS and NAC 639; or
    b. If performed by an employee of the ASC or RC, other than a registered pharmacist, performed:
        i. In accordance with the provisions of NRS and NAC 639;
        ii. In a location designated for compounding that is clean and disinfected before each act of compounding; and
        iii. By a person who has completed training for the type of compounding that will be performed.

I understand that I shall (NAC 639.4998):

a) Visit the ASC or RC at least once each month to:
    a. Evaluate the effectiveness of the policies and procedures established pursuant to NAC 693.4996; and
    b. Confirm that the ASC or RC is complying with those policies and procedures, the below provisions.
b) Maintain documentation of each visit that the pharmacist makes;
c) Conduct an audit at least once each month using a sufficient number of records of the ASC or RC, including, without limitation, records of patients and records relating to the purchasing, storing and dispensing of drugs and investigational drugs, which must be randomly selected, to determine whether:
    a. The records indicate that the drugs and investigational drugs are dispensed in a safe and effective manner in accordance with accepted standards of practice and the specifications of the manufacturer;
    b. Drugs and investigational drugs are diluted in accordance with accepted standards of practice or pursuant to the specifications of the manufacturer;
    c. The records demonstrate:
        i. That a discrepancy does not exist in the number of drugs and investigational drugs that are in vials designated by the manufacturer for a single use which are dispensed and the number of patients who receive such drugs and investigational drugs; and
        ii. That drugs, not including investigational drugs, which are in vials designated by the manufacturer for a single use and any remaining medication in those vials are discarded after use;
    d. The records demonstrate that drugs, not including investigational drugs, which are in vials designated by the manufacturer for more than one use are discarded when the medication in the vials has expired or not more than 28 days after the initial breach of the vial;
    e. The employees of the ASC or RC properly maintain accurate records relating to drugs and investigational drugs; and
    f. The employees of the ASC or RC properly monitor and maintain the perpetual inventory required pursuant to paragraph (d) of subsection 1 of NAC 639.4996; and
d) Submit a written report, including, without limitation, a written explanation, to the Board not later than 5 business days after the pharmacist determines that:
    a. The ASC or RC is violating a state or federal law which affects the care and safety of a patient;
    b. There is a discrepancy of 5 percent or more between the actual quantity of a controlled substance in the possession of the ASC or RC and the amount of the controlled substance that should be in the possession of the ASC or RC according to the records of the ASC or RC, including, without limitation:
        i. Purchase orders and invoices for the controlled substance;
        ii. Records which indicate the removal of the controlled substance from the storage area;
        iii. Patient records;
        iv. Records which indicate the return of the controlled substance to the manufacturer;
        v. Records which indicate that the controlled substance was destroyed; and
        vi. Any other record for the controlled substance;
    c. The recovery center or surgical center has intentionally or recklessly failed to create or maintain a record required by the policies and procedures established pursuant to NAC 639.4996;
    d. The recovery center or surgical center is administering a drug or an investigational drug in violation of accepted standards of practice or the specifications of the manufacturer; or
    e. The recovery center or surgical center is engaged in a practice which endangers the health, safety or welfare of a patient or employee of the recovery center or surgical center.

| Section 8: Personal and Professional History of the Employed/Contracted Pharmacist | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |
| 2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state? | | ✔ |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? | ✔ | |
| 4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # 3. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| 4/24/2002 | May 2002 | NV | Las Vegas | Clark |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| 02-036-RPH-S | | NV State Board of Pharmacy | | |
| **Reason/Charge** | | | | |
| Complaint concerning recors of PRN, Inc | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| Mary Grear | | | | |
| **Name of Business/Industry/Entity** | | | | |
| PRN, Inc. | | | | |

**Provide explanation below:**

A complaint was made concerning grants made by the Board of Pharmacy to PRN, Inc. under the care of Mary Grear, Executive Director. The Board of Pharmacy sent notice of a request for hearing to the wrong mailing address even though the corect address was on file at the Board Office. This resulted in my not being aware that I needed to appear until after the Board Meeting. I subsequently prepared the requested documents and submitted them to the Board Auditors who found no discrepencies in the funds granted by the Board of Pharmacy to PRN and ethe expense record under my administration. A rehearing was held and the case was closed finding all monies were accounted for the PRN, Inc. grants.

Mary Grear. RPh

Original signature of Employed/Contracted Pharmacist (copies or stamps not accepted)

5/17/2023

Date

| Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a) | ✓ | ✓ | | |
| • List the top four stockholders and their percent ownership. NRS 639.231(3) | ✓ | ✓ | | |
| • List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b) | | ✓ | | |
| • For General Partnerships, list the name of each partner. NAC 639.214(2)<br>• For Limited Partnerships, list the names of (NAC 639.214(3)):<br>○ All General Partners;<br>○ All Limited Partners who hold 10% or more of the interest. | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** from the Secretary of State's Office where the business is domiciled, dated within the last **6 months**. | ✓ | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/member/owner. Form found at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Submit a copy of your license, certification, permit or registration issued to your ASC or RC by the Nevada Division of Public and Behavioral Health of the Department of Health and Human Services.** | ✓ | ✓ | ✓ | ✓ |

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

James Lynch, MD

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

5/17/23

Date

| Board Use Only | Date Received: 6/29/23 | Amount: 500-CK-27472 |
|---|---|---|

1781

Effective Date : 01/01/2023
Expiration Date : 12/31/2023

State of Nevada
Department of Health and Human Services
Division of Public and Behavioral Health

License Number
461-ASC-31

**This Is To Certify That**

SURGERY CENTER OF RENO

343 ELM ST STE 100
RENO, NV 89503

**Is hereby licensed as a(n)**

**SURGICAL CENTER FOR AMBULATORY PATIENTS**

as provided for in Chapters 439 and 449 of the Nevada Revised Statutes and the Nevada Administrative Code and the standards, rules and regulations adopted by the Board of Health.

**This facility is licensed to provide the following:**

**Facility Type** : SURGICAL CENTER FOR AMBULATORY PATIENTS
AMBULATORY SURGICAL CENTER
CLASS E

**Endorsement** : CLASS - E

**Bed Information** : Operating Room - A - 5

ELIZABETH ANDERSEN / Administrator

HOMETOWN HEALTH MANAGEMENT COMPANY,SURGERY CENTER OF RENO, LLC

Lisa Sherych / Administrator

SECRETARY OF STATE

STATE OF NEVADA

# CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporation soles, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify, that the following is a list of all organizational documents on file in this office for

SURGERY CENTER OF RENO, LLC

| Organizational Documents on File | Filing Date |
|---|---|

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, SURGERY CENTER OF RENO, LLC, as a corporation duly organized under the laws of Nevada and existing under and by virtue of the laws of the State of Nevada since 10/14/2005, and is in good standing in this state.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 05/09/2023

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202305093639922
You may verify this certificate online at http://www.nvsos.gov

## Officers and Directors

Eric Boon
Matt Luke
Robert Gould
Chris Nicholas
James Lynch

## 10% or More Membership Interest Holders

Hometown Health Management Company
HOPCO Management Nevada LLC

# 4UU

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Pharmacist to Engage in the Practice of Pharmacy at a Site other than a Licensed Pharmacy

Rev (04/18/2023)

This application cannot be returned by fax or email.
We must have an original signature to process.

**Section 1: Select the following that applies to you.**

- ☐ I am employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity (If you marked this as your answer complete sections 1, 2, 3, 5, 7)
- ☐ I am a pharmacist who is employed by or under contract with a Nevada licensed pharmacy located within a hospital or correctional institution (If you marked this answer complete section 1, 2, 3, 5, 7)
- ☑ I am NOT employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity (If you marked this as your answer complete sections 1, 2, 4, 5, 6, 7)

**Section 2: General Information**

First: Trenie Middle: Lynn Last: Kunke

NV Pharmacist Registration # 16054

Telephone: [redacted] Email: [redacted]

**Section 3: Nevada Licensed Pharmacy as defined in NRS 639.012, or Nevada State Government Entity Information**

Pharmacy/State Government Entity Name: _____

NV Pharmacy License # (if Pharmacy) or State Issued License # (if State Government Entity): _____

Address: _____

City: _____ State: _____ Zip: _____

Employer Contact Name: _____

Employer Contact Telephone: _____ Employer Contact email: _____

**Section 4: Employer Information**

Name or Identity of Employer or Business as registered with the Nevada Secretary of State chapter 76 of NRS:

Aspen RxHealth

Address: 401 E Jackson St

City: Tampa State: FL Zip: 33602

Employer Contact Name: Aspen RxHealth

Employer Contact Telephone: 866-277-3679 Employer Contact email: pharmacists@aspenrxhealth.com

**Section 5: Place where the Pharmacist will Engage in the Practice of Pharmacy (list all sites)**

Name of Site (if applicable): Remote work from home

Address: [redacted] Lakewood Dr

City: Henderson State: NV Zip: 89012

Country/Territory/Province:

Is this a medical, residential, or business site? ☐ Medical ☒ Residential ☐ Business

Days of the week and hours services will be provided at this site? M-F 8am-8pm when I am available

Name of Site (if applicable):

Address:

City: State: Zip:

Country/Territory/Province:

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site?

Name of Site (if applicable):

Address:

City: State: Zip:

Country/Territory/Province:

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site?

Name of Site (if applicable):

Address:

City: State: Zip:

Country/Territory/Province:

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site?

Name of Site (if applicable):

Address:

City: State: Zip:

Country/Territory/Province:

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site?

Name of Site (if applicable):

Address:

City: State: Zip:

Country/Territory/Province:

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site?

(Use and make copies of this page if necessary)

**Section 6: NAC 639.403 A registered pharmacist who is NOT employed by or under contract with a pharmacy and who is NOT an employee of the State Government MUST complete this section.**

1. Provide a description of the services that you intend to provide at the site, to include only those services listed in Section 7 (A) of this application.

I will be delivering several clinic pharmacy services to Aspen RxHealth partners including medication therapy management, medication adherence and member education through yearly comprehensive medication reviews (CMRs) and targeted medication reviews (TMRs).

2. Provide the identification of the types of patients or other persons to whom you intend to provide services.

Aspen RxHealth contracts with health plans who are interested in using pharmacists to provide services to improve medication use and optimize health.

3. Provide a description of all resources, both paper and electronic, that will be available to you in the course of providing the services.

Consultation opportunities and patient selection are done inside the Aspen RxHealth mobile app. Aspen RxHealth handles all post-consultation work, including mailing the medication list and action plan to each patient.

4. Provide an explanation of the policy for users of the services when you are unavailable.

As a remote position, I am able to dictate how and when I work. There are no limits on patient volume and I am paid directly rather than through an employer or third party for each CMR or TMR that I complete and submit.

5. Provide an explanation of the policy regarding the confidentiality and security of the patient data that will be gathered, made, and maintained as part of the services which are provided, including without limitation, paper and electronic records.

Patient calls are auto dialed through the Aspen RxHealth mobile app on a secure line. All calls are recorded to comply with HIPPA and insurance regulations. All patient information and consultation notes are submitted through the app.

6. Provide a description of the business plan for the services provided.

1.Get credentialed through a background check and license verification, log into the app to view patient matches.
2.Make a list of patients and begin individualized outreach.
3.Get paid weekly for the clinical services that are delivered.
4.After each consult, the patient rates the quality of the consult and has the ability to "favorite" you for future outreach and care.

**Section 7: Laws pertaining to engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy. Please read Section 7 in its entirety. By signing this application, you attest you have read and understood the components in this section.**

**A. NAC 639 - For all registered pharmacists engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy**

1. While engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy, a registered pharmacist may perform only:
    a. The functions described in paragraphs (b), (c), (d) and (g) to (j), inclusive, of subsection 1 or NRS 639.0124, except for dispensing or administering drugs;
    b. The functions described in section 4 of LCB File No. R036.21, except for dispensing a self-administered hormonal contraceptive; and
    c. The administration of immunizations pursuant to a written protocol established in accordance with NAC 639.297 to 639.2978, inclusive.
2. A registered pharmacist who engages in the practice of pharmacy at a location other than the site of a licensed pharmacy shall:
    a. Provide written notice of the site of practice to the Executive Secretary in accordance with NAC 639.225 on this application; (NAC 639.225 states that a Nevada pharmacist, within 10 days after changing residence or place of practice, must give written notice of the change to the Board.)
    b. Ensure that the records of the registered pharmacist are made readily accessible to members of the Board and employees, agents and designees of the Board; and
    c. Comply with all applicable federal and state laws and regulations, including, without limitation:
        i. The Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, and the regulations adopted pursuant thereto, and any other applicable federal or state law concerning the privacy of information regarding health care; and
        ii. Requirements relating to the maintenance or records.
3. A registered pharmacist who engages in the practice of pharmacy at a location other than the site of a licensed pharmacy shall not maintain an inventory of drugs at that location.
4. A registered pharmacist shall not engage in the practice of pharmacy at a location other than the site of a licensed pharmacy if he or she:
    a. Serves as a managing pharmacist; or
    b. Provides pharmaceutical services at:
        i. A facility for modified medical detoxification, as defined in NRS 449.00385;
        ii. An independent center for emergency medical care, as defined in NRS 449.013;
        iii. A facility for intermediate care, as defined in NRS 449.0038;
        iv. A facility for skilled nursing, as defined in NRS 449.0039; or
        v. A surgical center for ambulatory patients, as defined in NRS 449.019.

**B. NAC 639 - For a registered pharmacist who is employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity.**

For a registered pharmacist who is employed by or under contract with a pharmacy or who is an employee of the State Government may engage in the practice of pharmacy at a location other than the site of a licensed pharmacy shall not engage in the practice of pharmacy at a location other than the site of a licensed pharmacy unless he or she is provided with the same computerized system and access to data regarding a patient for whom a prescription has been submitted that is available to a registered pharmacist in the pharmacy. Such data must include, without limitation:

a. A legible copy of the prescription that is available as an electronic copy or a scanned image in the computerized system of the pharmacy or by facsimile machine; and
b. Any information that is available in the computerized system of the pharmacy that is relevant or necessary for the registered pharmacist to provide pharmaceutical services.

**C. NAC 639.403 - For a registered pharmacist who is NOT employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity.**

For a registered pharmacist who is NOT employed by or under contract with a pharmacy or who is an employee of the State Government shall not engage in the practice of pharmacy at a site other than the site of a licensed pharmacy unless he or she obtains the approval of the Board to engage in the practice of pharmacy at a site other than the site of a licensed pharmacy. To request such approval, the registered pharmacist must submit this application. The application must be approved before a registered pharmacist may commence any practice.

**D. NAC 639.4916 - For a registered pharmacist who is employed by or under contract with a Nevada licensed pharmacy located within a hospital or correctional institution.**

1. A registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide the remote chart order processing services to the hospital or correctional institution that the pharmacy is required by NAC 639.4915 to provide must:
    a. Be trained in the policies and procedures of the hospital or correctional institution regarding all policies and procedures of the hospital or correctional institution with which the registered pharmacist must comply, including, without limitation, the provisions of pharmaceutical services, security, and confidentiality of patient records; and
    b. Be provided with the same computerized system and access to data regarding a patient for whom a chart order has been submitted that would be available to a registered pharmacist employe by the pharmacy located within the hospital or correctional institution, including, without limitation:
        i. The height, weight and age of the patient and any allergies that the patient may have;
        ii. The medical records regarding any medications prescribed to the patient;
        iii. The results of any relevant laboratory tests;
        iv. The health history and notes regarding physical examinations, to the extent that the information is available in the computerized system of the hospital or correctional institution;
        v. Any notes provided by a physician, nurse or other medical staff of the institution, to the extent that those notes are available in the computerized system of the hospital or correctional institution;
        vi. A legible copy of the chart order that is available through a scanned image in the computerized system of the hospital or correctional institution or by facsimile machine; and
        vii. Any other information that is available in the computerized system of the hospital or correctional institution that is relevant or necessary for the registered pharmacist to provide pharmaceutical services.
2. Before a registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution provides remote chart order processing services to the hospital or correctional institution, the registered pharmacist must review any relevant information regarding the patient for whom a chart order has been submitted. The registered pharmacist must, before approving a chart order to be filled, evaluate:
    a. The overutilization or underutilization of a medication;
    b. Therapeutic duplication;
    c. The appropriateness of the prescribed dosage and route of administration;
    d. The appropriateness of the directions for use of the medication;
    e. The appropriateness of the duration of the treatment with the prescribed medication;
    f. Any contraindication of the medication and a particular disease, ailment or allergy of the patient;
    g. Any contraindication or interactions between multiple medications prescribed for the patient; and
    h. The potential abuse or misuse of a medication.
3. A registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution provides remote chart order processing services to the hospital or correctional institution shall comply with the requirements of Section 7 (A) to the same extent as a registered pharmacist engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy pursuant to the provisions in Section 7 (B) and Section 7 (C).
4. In an emergency, a registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide remote chart order processing services to the hospital or correctional institution may render remote chart order processing services without being provided with all the information required by paragraph (b) of subsection 1 of Section 7 (D) if the registered pharmacist believes, in his or her professional judgement, that he or she has received sufficient information from the staff of the hospital or correctional institution to render the services.
5. A registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide remote chart order processing services to the hospital or correctional institution may refuse to approve the filling of a chart order if, in the judgement of the registered pharmacist, the chart order is not safe or reasonable for the patient. A registered pharmacist who refuses to approve the filling of a chart order pursuant to this subsection must notify the hospital or correctional institution as soon as practicable that he or she has refused to approve the filling of the chart order.
6. Each time that a registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide remote chart order processing services to the hospital or correctional institution

provides remote chart order processing services pursuant to this section, the registered pharmacist shall make a notation in the computerized system of the hospital or correctional institution that indicates:

a. The name or identifier of the registered pharmacist;
b. The date and time that the registered pharmacist provided the services and, if applicable, approved the filling of a chart order; and
c. The specific services provided by the registered pharmacist.

7. The managing pharmacist of a pharmacy located within a hospital or a correctional institution may limit the remote chart order processing services provided pursuant to this section (Section 7 (D)).

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I attest to the knowledge of and compliance with the guidelines of the Centers for Disease Control and Prevention concerning the prevention of transmission of infectious agents through safe and appropriate injection practices. NRS 639.132

I understand that Nevada law requires a registered pharmacist who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Trenie Kunke

Print Name

Kunke

Original Signature, no copies or stamps accepted

6/29/23

Date

| | |
|---|---|
| **Board Use Only** | Date Received: 7/5/23<br>For applicants who marked box 1 or 2 in Section 1: Executive staff to review, scanned into applicant file.<br>For applicants who marked box 3 in Section 1: Executive staff to review, place on consent agenda. |

# 4VV

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Pharmacist to Engage in the Practice of Pharmacy at a Site other than a Licensed Pharmacy

Rev (04/18/2023)

This application cannot be returned by fax or email.
We must have an original signature to process.

**Section 1: Select the following that applies to you:**

- ☐ I am employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity (If you marked this as your answer complete sections 1, 2, 3, 5, 7)
- ☐ I am a pharmacist who is employed by or under contract with a Nevada licensed pharmacy located within a hospital or correctional institution (If you marked this answer complete section 1, 2, 3, 5, 7)
- ☑ I am NOT employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity (If you marked this as your answer complete sections 1, 2, 4, 5, 6, 7)

**Section 2: General Information**

First: Zachary Middle: Robert Last: Rosko

NV Pharmacist Registration # 23317

Telephone: [redacted] Email: [redacted]

**Section 3: Nevada Licensed Pharmacy as defined in NRS 639.012, or Nevada State Government Entity Information**

Pharmacy/State Government Entity Name: _____

NV Pharmacy License # (if Pharmacy) or State Issued License # (if State Government Entity): _____

Address: _____

City: _____ State: _____ Zip: _____

Employer Contact Name: _____

Employer Contact Telephone: _____ Employer Contact email: _____

**Section 4: Employer Information**

Name or Identity of Employer or Business as registered with the Nevada Secretary of State chapter 76 of NRS:

Rosko Precision Health LLC

Address: 9012 Feather River Ct.

City: Las Vegas State: NV Zip: 89117

Employer Contact Name: Zach Rosko

Employer Contact Telephone: 208-243-9212 Employer Contact email: zrosko@rphgroup.org

**Section 5: Place where the Pharmacist will Engage in the Practice of Pharmacy (list all sites)**

Name of Site (if applicable): N/A

Address: [redacted] Feather River Ct

City: Las Vegas State: NV Zip: 89117

Country/Territory/Province: United States

Is this a medical, residential, or business site? ☐ Medical ☒ Residential ☐ Business

Days of the week and hours services will be provided at this site? M-Th 8AM - 7PM; Fri 8AM - 5PM; Sat 8AM - 1PM

Name of Site (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Country/Territory/Province: _____

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

Name of Site (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Country/Territory/Province: _____

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

Name of Site (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Country/Territory/Province: _____

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

Name of Site (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Country/Territory/Province: _____

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

Name of Site (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Country/Territory/Province: _____

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

(Use and make copies of this page if necessary)

**Section 6: NAC 639.403 A registered pharmacist who is NOT employed by or under contract with a pharmacy and who is NOT an employee of the State Government MUST complete this section.**

1. Provide a description of the services that you intend to provide at the site, to include only those services listed in Section 7 (A) of this application.

My initial focus will be the independent practice of pharmacy into Idaho via telehealth to provide pharmaceutical care services inclusive of prescribing drugs and devices, to Idaho residents under the authorities granted by my pharmacist licence in Idaho (P10492) and in accordance with the laws of the state of Idaho.

I also intend to expand my telehealth practice to include patients in NV on a more limited scale consistent with the scope of practice in NV. Services I would like to offer to NV residents include Part D Medication Therapy Management services, consultation on use of pharmacotherapy, prescribing of drugs for preventing the acquisition of human immunodeficiency virus and ordering laboratory tests necessary for therapy that uses such drugs, and potentially engaging in a Collaborative Practice Agreement with a NV licensed physician.

2. Provide the identification of the types of patients or other persons to whom you intend to provide services.

A. For initial services offered in Idaho: Patients throughout Idaho who self identify and refer as a patient in need of services we offer, patients referred by contracted Managed Medicare Plans for Part D MTM, and patients referred by pharmacies and medical practices we have established referral arrangements with. Patients must be able to consent to treatment and operate telehealth technology in order to establish a valid patient-practitioner relationship.
B. For services offered in NV: Patients in NV who self identify or are referred for services that we offer (other than CPA services). If a CPA service is established, a referral from the participating practitioner would be required.

3. Provide a description of all resources, both paper and electronic, that will be available to you in the course of providing the services.

Dynamed, Micromedex, Facts and Comparisons, Natural Medicine Database, PubMed, medical librarian on staff.

4. Provide an explanation of the policy for users of the services when you are unavailable.

For the initial services to be provided in ID, I have a contract pharmacist located in OR and licensed in ID who will provide call coverage and triage when I am unavailable to staff the service due to time off or sick time. Patients will additionally be established with a PCP and care cordinated with the primary team to manage in any downtime. Patients will additionally be notified to seek care in emergency situations with local Urgent Care/ED services. This notice will be on our phone message, website and in the content of our counseling.
NV services would similarly be coordinated with the primary team, triaged to urgent care/ED or for CPA services, coordinated with the referring provider. Before launching non-CPA NV services, I will be seeking a contract NV RPh.

5. Provide an explanation of the policy regarding the confidentiality and security of the patient data that will be gathered, made, and maintained as part of the services which are provided, including without limitation, paper and electronic records.

We have established a HIPAA and HITECH Compliant Privacy Policy and all staff will be appropriately trained. All clinical records will be maintained in the cloud based EMR that is Hitrust CSF Certified and messaging of PHI with patients will only occur via the embedded EMR patient messanger or mail to the address on file. Telehealth visits will be conducted via doxy.me HIPAA compliant AV technology. We have a ROI form to designate permissable contacts or permit release of any PHI outside of the permissions of HIPAA authorized use. BAAs have been established for all vendors who may come into contact with PHI in the course of our business. Staff will confirm two patient identifiers and review authorized individuals before release of any PHI verbally.

6. Provide a description of the business plan for the services provided.

All services will be via telehealth. Services will be provided on a fee for service basis (flat charge per service provided as defined by the fee schedule and CPT code for the service provided). Patients with multiple chronic conditions will be eligible to enroll in chronic care management subscription services where a monthly fee is charged for a group of services delivered over a month as defined by the CCM/PCM CPT codes. Idaho services will be on a self pay/no insurance basis as most major payers in ID cover telehealth only when provided in state. NV services may be provided on a cash pay or insurance basis.
Services will be deliverd by myself as the primary pharmacist clinician with assistance of an office manager / medical librarian for scheduling and clinical research. General, professional, and workmans comp insurance has been established.

**Section 7: Laws pertaining to engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy. Please read Section 7 in its entirety. By signing this application, you attest you have read and understood the components in this section.**

**A. NAC 639 - For all registered pharmacists engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy.**

1. While engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy, a registered pharmacist may perform only:
    a. The functions described in paragraphs (b), (c), (d) and (g) to (j), inclusive, of subsection 1 or NRS 639.0124, except for dispensing or administering drugs;
    b. The functions described in section 4 of LCB File No. R036.21, except for dispensing a self-administered hormonal contraceptive; and
    c. The administration of immunizations pursuant to a written protocol established in accordance with NAC 639.297 to 639.2978, inclusive.
2. A registered pharmacist who engages in the practice of pharmacy at a location other than the site of a licensed pharmacy shall:
    a. Provide written notice of the site of practice to the Executive Secretary in accordance with NAC 639.225 on this application; (NAC 639.225 states that a Nevada pharmacist, within 10 days after changing residence or place of practice, must give written notice of the change to the Board.)
    b. Ensure that the records of the registered pharmacist are made readily accessible to members of the Board and employees, agents and designees of the Board; and
    c. Comply with all applicable federal and state laws and regulations, including, without limitation:
        i. The Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, and the regulations adopted pursuant thereto, and any other applicable federal or state law concerning the privacy of information regarding health care; and
        ii. Requirements relating to the maintenance or records.
3. A registered pharmacist who engages in the practice of pharmacy at a location other than the site of a licensed pharmacy shall not maintain an inventory of drugs at that location.
4. A registered pharmacist shall not engage in the practice of pharmacy at a location other than the site of a licensed pharmacy if he or she:
    a. Serves as a managing pharmacist; or
    b. Provides pharmaceutical services at:
        i. A facility for modified medical detoxification, as defined in NRS 449.00385;
        ii. An independent center for emergency medical care, as defined in NRS 449.013;
        iii. A facility for intermediate care, as defined in NRS 449.0038;
        iv. A facility for skilled nursing, as defined in NRS 449.0039; or
        v. A surgical center for ambulatory patients, as defined in NRS 449.019.

**B. NAC 639 - For a registered pharmacist who is employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity.**

For a registered pharmacist who is employed by or under contract with a pharmacy or who is an employee of the State Government may engage in the practice of pharmacy at a location other than the site of a licensed pharmacy shall not engage in the practice of pharmacy at a location other than the site of a licensed pharmacy unless he or she is provided with the same computerized system and access to data regarding a patient for whom a prescription has been submitted that is available to a registered pharmacist in the pharmacy. Such data must include, without limitation:

a. A legible copy of the prescription that is available as an electronic copy or a scanned image in the computerized system of the pharmacy or by facsimile machine; and
b. Any information that is available in the computerized system of the pharmacy that is relevant or necessary for the registered pharmacist to provide pharmaceutical services.

**C. NAC 639.403 - For a registered pharmacist who is NOT employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity.**

For a registered pharmacist who is NOT employed by or under contract with a pharmacy or who is an employee of the State Government shall not engage in the practice of pharmacy at a site other than the site of a licensed pharmacy unless he or she obtains the approval of the Board to engage in the practice of pharmacy at a site other than the site of a licensed pharmacy. To request such approval, the registered pharmacist must submit this application. The application must be approved before a registered pharmacist may commence any practice.

**D. NAC 639.4916 - For a registered pharmacist who is employed by or under contract with a Nevada licensed pharmacy located within a hospital or correctional institution.**

1. A registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide the remote chart order processing services to the hospital or correctional institution that the pharmacy is required by NAC 639.4915 to provide must:
    a. Be trained in the policies and procedures of the hospital or correctional institution regarding all policies and procedures of the hospital or correctional institution with which the registered pharmacist must comply, including, without limitation, the provisions of pharmaceutical services, security, and confidentiality of patient records; and
    b. Be provided with the same computerized system and access to data regarding a patient for whom a chart order has been submitted that would be available to a registered pharmacist employe by the pharmacy located within the hospital or correctional institution, including, without limitation:
        i. The height, weight and age of the patient and any allergies that the patient may have;
        ii. The medical records regarding any medications prescribed to the patient;
        iii. The results of any relevant laboratory tests;
        iv. The health history and notes regarding physical examinations, to the extent that the information is available in the computerized system of the hospital or correctional institution;
        v. Any notes provided by a physician, nurse or other medical staff of the institution, to the extent that those notes are available in the computerized system of the hospital or correctional institution;
        vi. A legible copy of the chart order that is available through a scanned image in the computerized system of the hospital or correctional institution or by facsimile machine; and
        vii. Any other information that is available in the computerized system of the hospital or correctional institution that is relevant or necessary for the registered pharmacist to provide pharmaceutical services.
2. Before a registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution provides remote chart order processing services to the hospital or correctional institution, the registered pharmacist must review any relevant information regarding the patient for whom a chart order has been submitted. The registered pharmacist must, before approving a chart order to be filled, evaluate:
    a. The overutilization or underutilization of a medication;
    b. Therapeutic duplication;
    c. The appropriateness of the prescribed dosage and route of administration;
    d. The appropriateness of the directions for use of the medication;
    e. The appropriateness of the duration of the treatment with the prescribed medication;
    f. Any contraindication of the medication and a particular disease, ailment or allergy of the patient;
    g. Any contraindication or interactions between multiple medications prescribed for the patient; and
    h. The potential abuse or misuse of a medication.
3. A registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution provides remote chart order processing services to the hospital or correctional institution shall comply with the requirements of Section 7 (A) to the same extent as a registered pharmacist engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy pursuant to the provisions in Section 7 (B) and Section 7 (C).
4. In an emergency, a registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide remote chart order processing services to the hospital or correctional institution may render remote chart order processing services without being provided with all the information required by paragraph (b) of subsection 1 of Section 7 (D) if the registered pharmacist believes, in his or her professional judgement, that he or she has received sufficient information from the staff of the hospital or correctional institution to render the services.
5. A registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide remote chart order processing services to the hospital or correctional institution may refuse to approve the filling of a chart order if, in the judgement of the registered pharmacist, the chart order is not safe or reasonable for the patient. A registered pharmacist who refuses to approve the filling of a chart order pursuant to this subsection must notify the hospital or correctional institution as soon as practicable that he or she has refused to approve the filling of the chart order.
6. Each time that a registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide remote chart order processing services to the hospital or correctional institution

provides remote chart order processing services pursuant to this section, the registered pharmacist shall make a notation in the computerized system of the hospital or correctional institution that indicates:

a. The name or identifier of the registered pharmacist;
b. The date and time that the registered pharmacist provided the services and, if applicable, approved the filling of a chart order; and
c. The specific services provided by the registered pharmacist.

7. The managing pharmacist of a pharmacy located within a hospital or a correctional institution may limit the remote chart order processing services provided pursuant to this section (Section 7 (D)).

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I attest to the knowledge of and compliance with the guidelines of the Centers for Disease Control and Prevention concerning the prevention of transmission of infectious agents through safe and appropriate injection practices. NRS 639.132

I understand that Nevada law requires a registered pharmacist who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Zachary Rosko, PharmD, BCPS

Print Name

Original Signature, no copies or stamps accepted

06/23/2023

Date

| | |
|---|---|
| **Board Use Only** | Date Received: _____<br>For applicants who marked box 1 or 2 in Section 1: Executive staff to review, scanned into applicant file.<br>For applicants who marked box 3 in Section 1: Executive staff to review, place on consent agenda. |

# 4WW

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Pharmaceutical Technician (PT) Application

**Non-Refundable $50 fee**

Rev (06/22/2022)

**Section 1: General Information**

First: Alondra Middle: Pheoneeia Last: Holt

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☑ F ☐ X

Mailing Address: [redacted] West Cheyenne [redacted]

City: las vegas State: NV Zip: 89108

Telephone: [redacted] Email: [redacted]

**Section 2: Program of Training for Pharmaceutical Technicians (Complete this section ONLY if you have successfully completed an ASHP-approved PT school or training program.)**

Program/School Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Name of Program Director: _____

| Section 3: Application Qualifications (If you answer "NO" to any questions in this section, you CANNOT submit this application) | Yes | No |
|---|---|---|
| 1. Are you 18 years of age or older? | X | |
| 2. Are you a high school graduate or the equivalent? | X | |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | X |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | X |

| Section 5: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |

| Section 6: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration? | | X |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state? | | X |
| 3. Have you been the subject of a board citation or administrative action whether completed or pending in any state? | | X |
| 4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in any state? | | X |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____ Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| **Reason/Charge** | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| **Name of Business/Industry/Entity** | | | | |

**Provide explanation below:**

WALGREENS #06425
900 N. RANCHO DR.
LAS VEGAS, NV 89106

Original Signature (electronic, copies or stamps not accepted)

8/18/22 AH 3/30/23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I understand that Nevada law requires a registered pharmaceutical technician who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Original Signature, no copies or stamps accepted

Date 8/18/22

3/30/23

WALGREENS #06425
900 N. RANCHO DR.
LAS VEGAS, NV 89106

| Board Use Only | Date Received: 4-3-23 | Amount: 50.00 MO-2862870096-3 |
|---|---|---|

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Nevada Managing Pharmacist Certification of Training Hours for Pharmaceutical Technician in Training (PTT)

Rev (06/22/2022)

This form cannot be returned by fax or email.
We must have an original signature and fee to process.

**Section 1: Certification of PTT (NAC 639.242) MUST BE COMPLETED BY THE PHARMACY MANAGER**

Name of PTT: Alondra Holt
PTT License #: PT26396
Pharmacy Manager Name: Richard Daug
Pharmacy Manager License #: 19250
Name of Pharmacy: Walgreens
Pharmacy License #: PH 01063
Pharmacy Address: 6101 W. Lake Mead
City: Las Vegas
State: NV
Zip: 89108
Time period PTT employed (mm/yy-mm/yy): 5-13-2017

I certify to the Board that the above-named PTT has successfully completed 1500 hours of training and experience performing the tasks of a PT listed in NRS 639.1371 (3)(c) and NAC 639.245(2). The specific training and experience completed is listed below:

Data entry, filing, out window sales, retrieve new Rx, processing, inventory, TPR, follow daily Rx processing & legal/compliance to NV. state law.

Do you certify that the PTT is competent to perform the duties of a pharmaceutical technician? ☒Yes ☐No (If you answered "No" please explain why below):

I certify under penalty of perjury that the information contained on this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this form and any portion thereof is a public record unless otherwise declared confidential by law, and may be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020.

Richard Daug
Print Name (First, Last)

Original Signature of Managing Pharmacist, no copies or stamps accepted

3/30/23
Date

| Board Use Only | Date Received: 4-3-23 |
|---|---|

WALGREENS #06425
900 N. RANCHO DR.
LAS VEGAS, NV 89106

5. I hereby authorize _____ *(name of requesting agency)*, to submit a set of my fingerprints to the Nevada Department Public Safety, Records Bureau for the purpose of accessing and reviewing State of Nevada and FBI criminal history records that may pertain to me.

   In giving this authorization, I expressly understand that the records may include information pertaining to notations of arrest, detainments, indictments, information or other charges for which the final court disposition is pending or is unknown to the above referenced agency. For records containing final court disposition information, I understand that the release may include information pertaining to dismissals, acquittals, convictions, sentences, correctional supervision information and information concerning the status of my parole or probation when applicable.

6. I hereby release from liability and promise to hold harmless under any and all causes of legal action, the State of Nevada, its officer(s), agent(s) and/or employee(s) who conducted my criminal history records search and provided information to the submitting agency for any statement(s), omission(s), or infringement(s) upon my current legal rights. I further release and promise to hold harmless and covenant not to sue any persons, firms, institutions or agencies providing such information to the State of Nevada on the basis of their disclosures. I have signed this release voluntarily and of my own free will.

A reproduction of this authorization for release of information by photocopy, facsimile or similar process, shall for all purposes be as valid as the original.

In consideration for processing my application I, the undersigned, whose name and signature voluntarily appears below; do hereby and irrevocably agree to the above.

Applicant's Name: ***PLEASE PRINT***
Holt (Last Name) | Alondra (First Name) | Pheonecia (Middle)

ADDRESS: ***PLEASE PRINT***
5400 west Cheyenne Ave 1074
las vegas NV 89108

Applicant's Signature: Alondra Holt

Date: 3/30/2023

Submitting Agency: **Nevada State Board of Pharmacy**

Address: 985 Damonte Ranch Parkway Suite 206
Reno, Nevada 89521
Return Service Requested

WALGREENS #06425
900 N. RANCHO DR.
LAS VEGAS, NV 89106

Agency Representative: ***PLEASE PRINT***
Maynarikone (Last Name) | Jessette (First Name) | O (Middle)

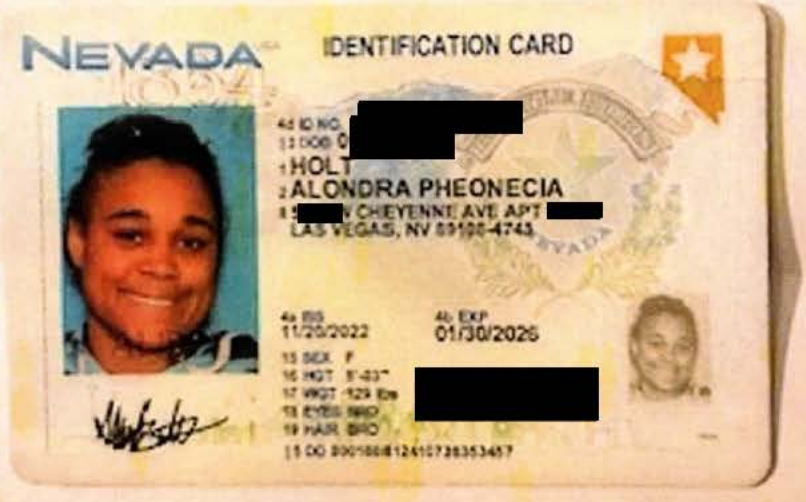
Agency Representative Signature:

Date: 4·3·23

0505RCCD-003(07/2017rev)
Fingerprint Background Waiver

To whom it may concern my name is alondra holt. im writting to explan back in 2010-2013 i was on a different path to were i was a stripper with my friends and was in wrong places and arrested never charged but have went to jail for soliciting and loitering i was in san jose and stockton ca and oakland i moved to las vegas in 2013 and changed my life around since i had my two children. i have not been to jail or anything for over 10 years . i did not lie on my application i just for got about my past .

alondra holt 07/15/2023




900 N. Rancho Dr.
Las Vegas, NV 89106
06425

# 4XX

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Pharmaceutical Technician (PT) Application
## Non-Refundable $50 fee

Rev (03/17/2023)

**Section 1: General Information**

First: Jennifer Middle: Jae Last: Jaycox

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address [redacted] Sunrise Bay Ave

City: North Las Vegas State: NV Zip: 89031

Telephone: [redacted] Email: [redacted]

**Section 2: Program of Training for Pharmaceutical Technicians (Complete this section ONLY if you have successfully completed an ASHP and Board approved PT school or training program.)**

Program/School Name: Pima Medical Institute

Address: 3333 E. Flamingo Rd

City: Las Vegas State: NV Zip: 89121

Name of Program Director: Lorinda Lohner

**Section 3: Employment Information**

Pharmacy Name: License #:

Address:

City: State: Zip:

| Section 4: Age and Education Requirements (You do not qualify to be a PT if you answer "NO" in this section.) | Yes | No |
|---|---|---|
| 1. Are you 18 years of age or older? | ✓ | |
| 2. Are you a high school graduate or the equivalent? | ✓ | |

High School Name: Adult Education Clark County Graduation Date OR Date GED obtained (mm/yy): 11/2019

Address: 2701 E St. Louis Ave

City: Las Vegas State: NV Zip: 89104

| Section 5: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |

| Section 6: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

| Section 7: Personal and Professional History | | |
|---|---|---|
| **Before answering the questions below, please INITIAL to the right to attest you have read and understand the following:**<br>**WARNING**<br>**You MUST provide truthful and complete responses to the questions on this application. If you omit information or provide false or misleading responses, including any failure to disclose past arrests or expunged convictions, this may be a basis for denial of your application and may result in disciplinary action against any other license or registration you hold from the Board.** | **Initials** | |
| | **Yes** | **No** |
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration? | | ✔ |
| 2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state even if the case or charge has been dismissed, sealed, acquitted, or expunged? | ✔ | |
| 3. Have you been the subject of a board citation or administrative action whether completed or pending in any state? | | ✔ |
| 4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in any state? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 7 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event MUST be provided.**

**This is in response to Question # 2. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| 03/27/2010 | 03/30/2010 | NV | Las Vegas | Clark |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| PC10M10186X | Las Vegas Justice Court |

| Reason/Charge |
|---|
| Battery ( Domestic Violence ) |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| State of Nevada / Defendant: Jennifer Jaycox | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

On 03/27/2010 my Boyfriend Justin Angel and I got into a disagreement about me drinking that morning. He had broke my computer and because I was angry about him breaking my property, I started tossing the laundry that was in a basket near by around the living room. Because of me tossing the clothes around he called the police. The police came while I was still intoxicated and In my current state my language towards the police was not as kind as it should of been while anserwing questions. As a result of the language I was using the police had said that because this was a Domestic Violence call that one of us had to be taken in, and since I was the intoxicated individual it resulted in me being under arrest.

Jennifer Jaycox
Original Signature (electronic, copies or stamps not accepted)

8/8/2023
Date

LAS VEGAS JUSTICE COURT

# CASE SUMMARY

## CASE NO. PC10M10186X

State of Nevada vs Jaycox, Jennifer

§ Location: **PreComplaint**
§ Judicial Officer: **Oesterle, Nancy C.**
§ Filed on: **03/27/2010**
§ Case Number History: **10M10186X**
§ ITAG Booking Number: **1000016979**
§ ITAG Case ID: **1139299**
§

### CASE INFORMATION

| Offense | Statute | Deg | Date | | |
|---|---|---|---|---|---|
| Jurisdiction: **Las Vegas Justice Court** | | | | Case Type: | **Misdemeanor** |
| 001. BATTERY (DOMESTIC VIOLENCE) | 200.481 | M | 03/27/2010 | Case Status: | **03/30/2010 Denied** |
| PCN: 0025180269 Sequence: 001 ACN: 1003271040 | | | | | |
| Arrest: 03/27/2010 | | | | Case Flags: | **Scope ID** |

### CASE ASSIGNMENT

**Current Case Assignment**

| | |
|---|---|
| Case Number | PC10M10186X |
| Court | PreComplaint |
| Date Assigned | 03/27/2010 |
| Judicial Officer | Oesterle, Nancy C. |

### PARTY INFORMATION

| | |
|---|---|
| **State of Nevada** | **State of Nevada** |
| **Defendant** | **Jaycox, Jennifer** |

### EVENTS & ORDERS OF THE COURT

| DATE | INDEX |
|---|---|
| **OTHER EVENTS AND HEARINGS** | |
| 03/27/2010 PreTrial Services Financial Affadavit and Information Sheet | |
| 03/27/2010 Standard Bail Set<br>*Ct1: $3000.00 Cash/3000.00 Surety* | |
| 03/27/2010 CTRACK Track Assignment JC06 | |
| 03/29/2010 Probable Cause Arrest Documents | |
| 03/31/2010 Minute Order | |

### FINANCIAL INFORMATION

No Financial Information Exists



*Printed on 08/08/2023 at 8:39 AM*

| Section 8: You MUST submit the documents below with your application base on your qualifications as a PT. | |
|---|---|
| **Select your qualification as a PT (please check a box).** | **Required documents to be submitted with your application.** |
| ☒ The successful completion of an ASHP-approved PT school or training program | a. Provide a copy of the certification of completion of the program. |
| ☐ **Active practice in good standing** in another state as a PT, and the successful completion of at least 1,500 hours of employment as a PT in a pharmacy in that state performing the duties set forth in paragraph (c) of subsection 3 of NRS 639.1371, which must be verified by a **signed affidavit** by the managing pharmacist of the pharmacy. | a. Provide a copy of your PT registration, license, or certificate (if it is a requirement by that state to practice as a PT), which must be current, active, and in good standing.<br>b. Provide the signed affidavit from your managing pharmacist that you have completed at least 1,500 hours of employment as a PT in a pharmacy **in that state** (see form provided in this application). |
| ☐ The successful completion of at least 1,500 hours of training and experience as a registered pharmaceutical technician in training (PTT), performing the duties set forth in paragraph (c) of subsection 3 of NRS 639.1371, in Nevada licensed pharmacies, which must be verified by the managing pharmacist of the pharmacy. | a. Provide the signed form from your managing pharmacist that you have completed 1,500 hours of training and experience in a pharmacy **in this state** as a registered PTT (see form provided in this application). |
| ☐ The successful completion of a pharmaceutical technician training program conducted by a branch of the U.S. Armed Forces, the Indian Health Service of United States Department of Health and Human Services or the U.S. Department of Veterans Affairs. | a. Provide a copy of the certification of completion of the program. |

**Section 9: Fingerprints for a background check. ALL APPLICANTS MUST COMPLETE THIS SECTION. NRS 639.1371**

**In addition to the requirements in section 7, submit fingerprints for a background check** by following the instructions https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/FP%20Instructions%20NRS%20639.127%20639.1371.pdf

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I understand that Nevada law requires a registered pharmaceutical technician who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Jennifer Jaycox
Print Name

Jennifer Jaycox
Original Signature, no copies or stamps accepted

5/30/23
Date

| Board Use Only | Date Received: 6/15/23 | Amount: $50 - MO - 19-5455 13306 |
|---|---|---|

# Pima Medical Institute

*ON RECOMMENDATION OF THE FACULTY AND BY AUTHORITY*
*OF THE BOARD OF DIRECTORS THIS*

# Certificate

*IS HEREBY AWARDED TO*

## Jennifer Jaycox

*FOR SATISFACTORY COMPLETION OF*

## Pharmacy Technician

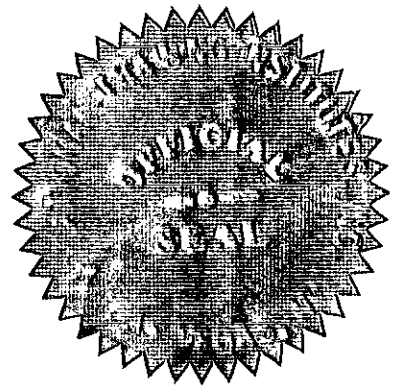
**33.5 Semester Credit Hours**

*IN ACCORDANCE WITH STANDARDS AND PROCEDURES SET BY THIS INSTITUTION*

*SIGNED AND GIVEN UNDER OUR HAND*

*AT* Las Vegas Nevada

*THIS* 25th *DAY OF* May, 2023



Lisa J Owens
*DIRECTOR*

*FACULTY*

# 4YY

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Pharmaceutical Technician (PT) Application

Non-Refundable $50 fee

Rev (06/22/2022)

**Section 1: General Information**

First: Vesta Middle: Denise Last: Johnson

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted] Boulder Highway, Apt # [redacted]

City: Las Vegas State: NV Zip: 89122

Telephone: [redacted] Email: [redacted]

**Section 2: Program of Training for Pharmaceutical Technicians (Complete this section ONLY if you have successfully completed an ASHP-approved PT school or training program.)**

Program/School Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Name of Program Director: _____

| Section 3: Application Qualifications (If you answer "NO" to any questions in this section, you CANNOT submit this application) | Yes | No |
|---|---|---|
| 1. Are you 18 years of age or older? | ✓ | |
| 2. Are you a high school graduate or the equivalent? | ✓ | |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | N/A | N/A |

| Section 5: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 6: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

| Section 7: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration? | | |
| 2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state even if the case or charge has been dismissed, sealed, acquitted, or expunged? | | |
| 3. Have you been the subject of a board citation or administrative action whether completed or pending in any state? | | |
| 4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in any state? | | |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 7 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event MUST be provided.**

This is in response to Question # 2 . **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| May 2010 | May/2010 | WI | Glendale | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| N/A | |

| Reason/Charge |
|---|
| Cashing bad check |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| N/A | N/A |

| Name of Business/Industry/Entity |
|---|
| Glendale Police Department |

**Provide explanation below:**

During this time I was banking with Educators Credit Union. I remember receiving a check in the mailbox for about $900. Mr being young and in need of cash, I went and cashed the check at my bank. The check was a bad check. So in return I was summoned to go to the station to provide a statement and plea (guilty) I lost my account, had to repay the credit Union and also be charged a misdemeanor. I have no record from this case taken it was 13 years ago.

Vesta Johnson

Original Signature (electronic, copies or stamps not accepted)

March 28, 2023

Date

CITY OF GLENDALE
POLICE DEPARTMENT

5909 North Milwaukee River Parkway
Glendale, Wisconsin 53209-3815
(414) 228-1753
Fax (414) 228-1707
Email: police@glendalewi.gov

Open Records Request for a Police Report

Dear Requestor;

This letter is in response to your open records request. The reports requested will be provided to you in conformity with the Wisconsin Statutes and the Drivers Privacy Protection Act, 18 U.S.C. § 2721, et. seq. Personal information, as defined in 18 U.S.C. § 2725(3), and highly restricted personal information, as defined in 18 U.S.C. § 2725(4), will be redacted from the reports. Personal information and highly restricted personal information will be released only with the express consent of the individuals to whom the information pertains.

In accordance with §19.35(4) of the Wisconsin Statutes, you are advised that if you consider any portion of this response to constitute a denial of your request, the denial is subject to review by mandamus pursuant to the provisions of § 19.37(1) of the Wisconsin Statutes or upon application to the Attorney General or the District Attorney.

If you have any questions regarding your open records request, please contact us at (414) 228-1753.

Sincerely,

Records Department
Glendale Police Department

10-004614
Fraud Supp (1)
Det Bryan C Bichler

On Wednesday, 03-03-2010 I received a packet of info Educators Credit Union Security Officer Angela M Langdon [redacted] The information documented the following:

On 11-04-2009 a person identified as Vesta Denise Johnson (f/b 08-08-1990) cashed check #5041 at Educators Credit Union for $850.75. The check was purportedly drawn on the Legacy Bank account of Great Wealth LLC, DBA Pondersosa, 2730 N Martin Luther King Dr, Milwauk[redacted]e transaction was completed by bank employee Destiny L Halbert [redacted].

Check #5041 was returned to Educators Credit Union as an account closed check. A Legacy Bank Security Alert advised that the account was closed in September of 2009 due to fraud.

Johnson attempted to cash another check some time between 11-04-2009 and 11-17-2009 at the Glendale branch. The check was purportedly drawn on the Wells Fargo Bank account of Green Bay Beef, LLC of Green Bay, WI. She was denied the transaction due to the cashing of check #5041. She attempted to cash the same Wells Fargo check at the St Joseph's Hospital branch. The validity of the Wells Fargo check has not yet been determined.

At the time Johnson cashed the Legacy Bank check she had $2.02 in her account. A demand letter was sent to Johnson at 1924 N 19th St on 11-17-2009. No response was received.

The packet from Langdon included original check #5041. The back of the check w[redacted] the name Vesta Johnson. It also showed the social security number [redacted]

A search of the on-line data bank Accurint showed the social security number assigned to Vesta D Johnson. An additional entry showed the name Valerie D Johnson, also at 1924 N 19th St. It appeared, based on additional information, that Valerie might be Vesta's mother.

The packet included two video still photos showing the transaction on 11-04-2009. A comparison of the video photos to a photo of Vesta D Johnson obtained from WI DOT confirmed that Johnson was the person who completed the transaction.

Educators Credit Union has suffered a loss of $863.43.

Vesta Johnson is not wanted. She has suspended DL status and no CIBR.

The original check was inventoried under #45329. The packet of

10-004614
Fraud Supp (4)
Det Bryan C Bichler

On Wednesday, 05-12-2010 I spoke with Angela Langdon. Langdon advised that Vesta Johnson has reimbursed Educators Credit Union for the full loss amount. I forwarded the information to the Glendale Municipal Court.
BCB-728

10-004614
Fraud Supp (3)
Det Bryan C Bichler

On Friday, 04-09-2010 at 6:42pm, Vesta Denise Johnson came to Glendale PD regarding this incident. I escorted her to an interview room. I read the Miranda right to her from a DOJ issued card. She stated she understood the rights and agreed to speak with me.

Johnson admitted that she was the person shown in the Educators Credit Union video photos, which showed the cashing of the Great Wealth LLC check. Johnson claimed she could not recall exactly how she obtained the check, but believed she received it in the mail. Johnson admitted that she has never worked for a company called Great Wealth LLC, Pondersosa or Ponderosa. She stated that she didn't notice that Ponderosa was spelled incorrectly on the check. She admitted that none of the companies would have had a reason to owe her money or write her a check. She stated that she simply received it in the mail and thought she would try cashing it. Johnson claimed that she did not receive the demand letter from Educators Credit Union and claimed not to know the check came back to the bank as Account Closed. Johnson claimed to have no memory of trying to cash the Green Bay Beef check at two locations.

Johnson was booked for Forgery. I issued municipal citation #N1045335 for Forgery/Uttering to Johnson. I provided her with Angela Langdon's mailing information and advised Johnson that it might benefit her during court proceedings if she repaid the loss prior to the court date. Johnson was then released into the lobby.
BCB-728

10-004614
Fraud Supp (2)
Det Bryan C Bichler

On Monday, 03-15-2010 at 5:30pm, I attempted contact with Vesta Johnson at 2373 N 52nd St #9. I left a card on the door.

At 5:55pm I spoke with Johnson by phone. She agreed to come to Glendale PD on Sunday, 03-21-2010 at 5pm to meet with me regarding the Great Wealth LLC check.
BCB-728

10-004614
Fraud Supp (1)
Det Bryan C Bichler

On Wednesday, 03-03-2010 I received a packet of info Educators Credit Union Security Officer Angela M Langdon [redacted] The information documented the following:

On 11-04-2009 a person identified as Vesta Denise Johnson (f/b 08-08-1990) cashed check #5041 at Educators Credit Union for $850.75. The check was purportedly drawn on the Legacy Bank account of Great Wealth LLC, DBA Pondersosa, 2730 N Martin Luther King Dr, Milwauk[redacted] e transaction was completed by bank employee Destiny L Halbert [redacted].

Check #5041 was returned to Educators Credit Union as an account closed check. A Legacy Bank Security Alert advised that the account was closed in September of 2009 due to fraud.

Johnson attempted to cash another check some time between 11-04-2009 and 11-17-2009 at the Glendale branch. The check was purportedly drawn on the Wells Fargo Bank account of Green Bay Beef, LLC of Green Bay, WI. She was denied the transaction due to the cashing of check #5041. She attempted to cash the same Wells Fargo check at the St Joseph's Hospital branch. The validity of the Wells Fargo check has not yet been determined.

At the time Johnson cashed the Legacy Bank check she had $2.02 in her account. A demand letter was sent to Johnson at 1924 N 19th St on 11-17-2009. No response was received.

The packet from Langdon included original check #5041. The back of the check w[redacted] the name Vesta Johnson. It also showed the social security number [redacted]

A search of the on-line data bank Accurint showed the social security number assigned to Vesta D Johnson. An additional entry showed the name Valerie D Johnson, also at 1924 N 19th St. It appeared, based on additional information, that Valerie might be Vesta's mother.

The packet included two video still photos showing the transaction on 11-04-2009. A comparison of the video photos to a photo of Vesta D Johnson obtained from WI DOT confirmed that Johnson was the person who completed the transaction.

Educators Credit Union has suffered a loss of $863.43.

Vesta Johnson is not wanted. She has suspended DL status and no CIBR.

The original check was inventoried under #45329. The packet of

| Section 6: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration? | | ✓ |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state? | | ✓ |
| 3. Have you been the subject of a board citation or administrative action whether completed or pending in any state? | | ✓ |
| 4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in any state? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # N/A **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| Reason/Charge | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| Name of Business/Industry/Entity | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

Date

| **Section 7: You MUST submit the documents below with your application base on your qualifications as a PT.** | |
|---|---|
| **Select your qualification as a PT (please check a box).** | **Required documents to be submitted with your application.** |
| ☐ The successful completion of an ASHP-approved PT school or training program | a. Provide a copy of the certification of completion of the program. |
| ☐ Registration as a PT in another state if the requirements for registration in that state are equivalent to the requirements of this state, and the successful completion of at least 240 hours of employment as a PT in a pharmacy in that state, which must be verified by a signed affidavit by the managing pharmacist of the pharmacy. | a. Provide a copy of your PT registration, which must be current, active and in good standing.<br>b. Include the signed affidavit from your managing pharmacist that you have completed at least 240 hours of employment as a PT in a pharmacy **in that state** (see form provided in this application). |
| ☐ If the state in which the applicant has been employed does not offer registration, licensure or certification as a PT, the successful completion of at least 1,500 hours of experience in a pharmacy in that state performing the duties set forth in paragraph (c) of subsection 3 of NRS 639.1371 during the 3 years immediately preceding the date on which his or her application is submitted, which must be verified by a signed affidavit by the managing pharmacist of the pharmacy. And the successful completion of at least 350 hours of employment in a pharmacy in this state as a registered PTT, which must be verified by the managing pharmacist of the pharmacy. | a. Provide the signed affidavit from your managing pharmacist that you have completed at least 1,500 hours of employment as a PT in a pharmacy **in that state** (see form provided in this application).<br>b. Provide a signed form from your managing pharmacist that you have completed 350 hours of employment in a pharmacy **in this state** as a registered PTT (see form provided in this application). |
| ☐ The successful completion of at least 1,500 hours of training and experience as a registered PTT employed in Nevada licensed pharmacies, which must be verified by the managing pharmacist of the pharmacy. | a. Provide a signed form from your managing pharmacist that you have completed 1,500 hours of employment in a pharmacy **in this state** as a registered PTT (see form provided in this application). |
| ☐ The successful completion of a pharmaceutical technician training program conducted by a branch of the U.S. Armed Forces, the Indian Health Service of United Sates Department of Health and Human Services or the U.S. Department of Veterans Affairs. | a. Provide a copy of the certification of completion of the program. |
| ☐ Certification by the Pharmacy Technician Certification Board (PTCB) or the National Healthcareer Association (NHA) as a PT and completion of at least 500 hours of training and experience as a registered PTT employed in Nevada licensed pharmacies, which must be verified by the managing pharmacist of the pharmacy. | a. Provide a copy of your PTCB or NHA certification (i.e. CPhT or ExCPT certification);<br>b. Provide a signed form from your managing pharmacist that you have completed 500 hours of employment in a pharmacy **in this state** as a registered PTT (see form provided in this application). |

**Section 8: In addition to the requirements in section 7, submit fingerprints for a background check** by following the instructions https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%207-1-19.pdf.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I understand that Nevada law requires a registered pharmaceutical technician who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Original Signature, no copies or stamps accepted

1-13-2022
Date

| Board Use Only | Date Received: 1.31.23 | Amount: 50.00 MO - 7787427103 |
|---|---|---|

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Nevada Managing Pharmacist Certification of Training Hours for Pharmaceutical Technician in Training (PTT)

Rev (06/22/2022)

This form cannot be returned by fax or email.
We must have an original signature and fee to process.

**Section 1: Certification of PTT (NAC 639.242) MUST BE COMPLETED BY THE PHARMACY MANAGER**

Name of PTT: Vesta Johnson PTT License #: PT 25629

Pharmacy Manager Name: Ann Togashi Pharmacy Manager License #: 19548

Name of Pharmacy: CVS Pharmacy Pharmacy License #: PH01976

Pharmacy Address: 4490 Paradise Road

City: Las Vegas State: NV Zip: 89169

Time period PTT employed (mm/yy-mm/yy): 10/2021 - current

I certify to the Board that the above-named PTT has successfully completed 1,500 hours of training and experience performing the tasks of a PT listed in NRS 639.1371 (3)(c) and NAC 639.245(2). The specific training and experience completed is listed below:

Vesta has completed 1500 hours working at retail cvs locations. Her duties and experience includes typing + filling prescriptions, selling out prescriptions at the register, stocking + maintaining inventory in pharmacy and OTC. Answering phones, making patient care phone calls. Filing and organizing prescriptions, invoices, maintaing general cleanliness + keeping pharmacy hygiene.

Do you certify that the PTT is competent to perform the duties of a pharmaceutical technician? ☑ Yes ☐ No (If you answered "No" please explain why below):

I certify under penalty of perjury that the information contained on this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this form and any portion thereof is a public record unless otherwise declared confidential by law, and may be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020.

Ann Togashi

Print Name (First, Last)

Original Signature of Managing Pharmacist, no copies or stamps accepted

1-13-23

Date

| Board Use Only | Date Received: 1.31.23 |
|---|---|

# 4ZZ

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Pharmaceutical Technician (PT) Application

**Non-Refundable $50 fee**

Rev (01/18/2023)

**Section 1: General Information**

First: Rebeka Middle: Last: Gjakhyan

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted] Sierra Blue ct

City: Las Vegas NV State: NV Zip: 89141

Telephone: [redacted] Email: [redacted]

**Section 2: Program of Training for Pharmaceutical Technicians (Complete this section ONLY if you have successfully completed an ASHP and Board approved PT school or training program.)**

Program/School Name:

Address:

City: State: Zip:

Name of Program Director:

**Section 3: Employment Information**

Pharmacy Name: Walgreens License #: PH02371

Address: 8595 W Warm Springs

City: Las Vegas State: NV Zip: 89113

| Section 4: Age and Education Requirements (You do not qualify to be a PT if you answer "NO" in this section.) | Yes | No |
|---|---|---|
| 1. Are you 18 years of age or older? | X | |
| 2. Are you a high school graduate or the equivalent? | X | |

High School Name: Spring Valley High School Graduation Date OR Date GED obtained (mm/yy): 06/2014

Address: 3750 S Buffalo Dr

City: Las Vegas State: NV Zip: 89147

| Section 5: Military Service (NRS 622.120): | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |

| Section 6: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✔ |

| Section 7: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration? | | ✔ |
| 2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state even if the case or charge has been dismissed, sealed, acquitted, or expunged? | ✔ | |
| 3. Have you been the subject of a board citation or administrative action whether completed or pending in any state? | | ✔ |
| 4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in any state? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 7 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event MUST be provided.**

This is in response to Question # 2. **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| 11/15/2020 | 11/17/2021 | NV | Las Vegas | Clark |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| 20-CR-034068 | Las Vegas Metro Police Department |

| Reason/Charge |
|---|
| Reckless driving w/disregard safety of pers/prop |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| State of Nevada/Rebeka Ojakhyan | Misdemeanor CR |

| Name of Business/Industry/Entity |
|---|
| State of Nevada |

**Provide explanation below:**
See the attached documents.

Original Signature (electronic, copies or stamps not accepted)

05/15/2023
Date

# REGISTER OF ACTIONS

## CASE NO. 20-CR-034068

**State of Nevada vs. OJAKHYAN, REBEKA**

| | |
|---|---|
| Case Type: | **Misdemeanor CR** |
| Subtype: | **DUI Case** |
| Date Filed: | **07/14/2021** |
| Location: | |
| Case Number History: | **20-PC-034068** |
| | **20-CR-034068** |
| Arresting Agency Event Number: | **201100064056** |
| DA CMS Case ID: | **20-49407** |
| DA CMS Display ID: | **202049806C** |
| ITAG Booking Number: | **2000049250** |
| ITAG Case ID: | **2268890** |
| Odyssey Case ID: | **13330127** |

## PARTY INFORMATION

**Defendant** **OJAKHYAN, REBEKA**

DOB: [redacted]

**Lead Attorneys**
**Damian Sheets**
*Retained*
702-988-2600(W)

**State of Nevada** **State of Nevada**

## CHARGE INFORMATION

| Charges: OJAKHYAN, REBEKA | Statute | Level | Date |
|---|---|---|---|
| 1. Reckless driving w/disregard safety of pers/prop [56810] | 14.24.010A | Misdemeanor | 11/15/2020 |

## EVENTS & ORDERS OF THE COURT

**DISPOSITIONS**

11/17/2021 **Plea** (Judicial Officer: Baucum, Suzan)
1. Reckless driving w/disregard safety of pers/prop [56810]
Nolo Contendere

11/17/2021 **Disposition** (Judicial Officer: Baucum, Suzan)
1. Reckless driving w/disregard safety of pers/prop [56810]
Adjudication Deferred

11/17/2021 **Interim Sentence - Final Disposition Pending** (Judicial Officer: Baucum, Suzan)
1. Reckless driving w/disregard safety of pers/prop [56810]
Condition - Adult:
1. Suspended Jail Sentence, 30 days 11/17/2021, Active 11/17/2021
2. Stay Out of Trouble, 11/17/2021, Active 11/17/2021
3. DUI School, MESA FAMILY COUNSELING 11/17/2021, , Satisfied 12/09/2021
4. Victim Impact Panel, 11/17/2021, , Satisfied 12/22/2021
5. Community Service, 86 Hours In Lieu of fine - $140 fees to be paid 11/17/2021, Active 11/17/2021
6. Defendant Sentenced to 2 Days Jail, with 2 Days Credit for Time Served 11/17/2021, , Satisfied 01/04/2022
7. If Defendant picks up a new DUI during this case, or is arrested or cited for Driving with a Suspended/Revoked License, Court will impose 180 days jail. 11/17/2021, Active 11/17/2021
8. If so, to be amended to Reckless Driving, and credit for time served; if not, Conviction 11/17/2021, Active 11/17/2021

Fee Totals:

| | |
|---|---|
| Cash Bond Criminal Deferred Disposition Fee | $1,000.00 |
| Fee Totals $ | $1,000.00 |

01/05/2022 **Amended Plea** (Judicial Officer: Zimmerman, Ann E.) Reason: Per Negotiations
1. Reckless driving w/disregard safety of pers/prop [56810]
Nolo Contendere

01/05/2022 **Amended Disposition** (Judicial Officer: Zimmerman, Ann E.) Reason: Per Negotiations
1. Reckless driving w/disregard safety of pers/prop [56810]
Guilty as Amended

01/05/2022 **Amended Misdemeanor Sentence** (Judicial Officer: Zimmerman, Ann E.) Reason: Per Negotiations
1. Reckless driving w/disregard safety of pers/prop [56810]
Condition - Adult:
1. Suspended Jail Sentence, 30 days 11/17/2021, Closed 01/05/2022
2. Stay Out of Trouble, 11/17/2021, Satisfied 01/05/2022
3. DUI School, MESA FAMILY COUNSELING 11/17/2021, , Satisfied 12/09/2021
4. Victim Impact Panel, 11/17/2021, , Satisfied 12/22/2021
5. Community Service, 86 Hours In Lieu of fine - $140 fees to be paid 11/17/2021, Closed 01/05/2022
6. Defendant Sentenced to 2 Days Jail, with 2 Days Credit for Time Served 11/17/2021, , Satisfied 01/04/2022

7. If Defendant picks up a new DUI during this case, or is arrested or cited for Driving with a Suspended/Revoked License, Court will impose 180 days jail. 11/17/2021, Closed 01/05/2022
8. If so, to be amended to Reckless Driving, and credit for time served; if not, Conviction 11/17/2021, Closed 01/05/2022
9. Credit for Time Served, 01/05/2022, Satisfied 01/05/2022

Fee Totals:

| | |
|---|---|
| AA Fees | $140.00 |
| County Fine-Criminal | $860.00 |
| Fee Totals $ | $1,000.00 |

**OTHER EVENTS AND HEARINGS**

11/15/2020 **Original Track Assignment JC02**
11/15/2020 **DA Request for Prosecution**
*Request for Prosecution Sent to DA*
11/15/2020 **Case Assignment Sent**
*Case Assignment Sent*
11/15/2020 **Administrative Own Recognizance Release**
11/15/2020 Release Agreement
11/16/2020 Probable Cause Review Packet - Initial Appearance Court
11/16/2020 Probable Cause Review Packet - Initial Appearance Court
*Updated*
12/15/2020 Notice of Confirmation of Counsel
*Notice of Confirmation of Counsel*
01/19/2021 Status Check on Filing of Criminal Complaint (7:30 AM) (Judicial Officer Baucum, Suzan)
*O/R*
Parties Present
Result: Matter Heard
01/19/2021 **Counsel Confirms as Attorney of Record**
*K. Bernstein, Esq for D. Sheets, Esq*
01/19/2021 **State Requests Additional Time for Filing of Complaint**
01/19/2021 **Continued for Status Check on filing of Criminal Complaint**
01/19/2021 Minute Order - Department 13
07/14/2021 Criminal Complaint
07/21/2021 Arraignment (7:30 AM) (Judicial Officer Baucum, Suzan)
*O/R*
Parties Present
Result: Matter Heard
07/21/2021 **Arraignment Completed**
*Advised of Charges on Criminal Complaint, Waives Reading of Criminal Complaint*
07/21/2021 **Plea of Not Guilty Entered**
07/21/2021 **Matter Not Negotiated - Preliminary Hearing/Trial Date Set**
07/21/2021 Minute Order - Department 13
11/17/2021 Bench Trial (8:00 AM) (Judicial Officer Baucum, Suzan)
*O/R*
Parties Present
Result: Matter Heard
11/17/2021 **Defendant Waives the Right to Trial**
11/17/2021 Admonishment of Rights - DUI
*Filed in open Court*
11/17/2021 **Status Check on Requirements**
11/17/2021 Minute Order - Department 13
11/24/2021 **Attestation**
12/28/2021 Motion
*Motion to Close Case*
01/01/2022 **Administrative Reassignment to Department 8**
*Case Reassigned From Department 13 (Judge Suzan Baucum)*
01/05/2022 Motion (7:30 AM) (Judicial Officer Zimmerman, Ann E.)
Parties Present
Result: Matter Heard
01/05/2022 **Plea entered by Counsel**
01/05/2022 **Judgment Entered**
01/05/2022 **Cash Bond Ordered Transferred**
*to satisfy fine imposed*
01/05/2022 **Future Court Date Vacated**
*3/16/22 at 7:30 am*
01/05/2022 **Case Closed - Requirement(s) Completed**
01/05/2022 Minute Order - Department 08
01/11/2022 Notice of Disposition and Judgment
01/11/2022 Report of Conviction for Violation of Motor Vehicle Laws
03/16/2022 *CANCELED* **Status Check on Requirements** (8:00 AM) (Judicial Officer Zimmerman, Ann E.)
*Vacated*
*OR*

## FINANCIAL INFORMATION

**Defendant** OJAKHYAN, REBEKA

| | |
|---|---|
| Total Financial Assessment | 1,005.50 |
| Total Payments and Credits | 1,005.50 |
| **Balance Due as of 05/15/2023** | **0.00** |

| | | | | |
|---|---|---|---|---|
| 11/25/2021 | Web | Receipt # CCS-2021-26731 | OJAKHYAN, REBEKA | (1,000.00) |
| 11/25/2021 | Transaction Assessment | | | 5.50 |
| 11/25/2021 | Matterhorn Court Convenience Fee | Receipt # CCS-2021-26732 | OJAKHYAN, REBEKA | (0.50) |
| 11/25/2021 | Matterhorn Credit | | | (5.00) |
| 01/05/2022 | Transaction Assessment | | | 1,000.00 |

RECEIVED
DEC 2 2 2021
BY:

STOP DUI VIP
PAID

Court Referral
- [x] Las Vegas Justice
- [ ] Las Vegas Municipal
- [ ] Henderson Justice
- [ ] Henderson Municipal
- [ ] Boulder City Justice
- [ ] Boulder City Municipal
- [ ] N. Las Vegas Justice
- [ ] N. Las Vegas Municipal
- [ ] Clark County District Court
- [ ] Juvenile
- [ ] Other _____

## STOP DUI VICTIM IMPACT PANEL

Contact: (702) 376-1238 Monday-Thursday 8:00AM-5:00PM * Closed Weekends & Holidays.
*DEFENDANTS ARE RESPONSIBLE FOR ENSURING ALL INFORMATION IS CORRECT*

Case No: 20-CR-034068

DEFENDANTS COPY

Ojakhyan
Last Name (Print) AKA

Rebeka
First Name (Print) Middle Name DOB [redacted]

FEE: 75.00 Cash or money order only.
STOP DUI does not waive attendance fees without an original official court waiver. Guests may attend for 25.00.

English Class: 2nd Wednesday of the month, 302 Tin Street, Henderson, NV 89015. Located in the Special Programs modular building off Water Street and Basic Rd.

English/Spanish Classes: 4th Wednesday of the month, 302 Tin Street, Henderson, NV 89015, Located in the Special Programs modular building off Water Street and Basic Rd.

Class dates are listed on www.stopdui.org

Check in 6:00 PM * Classes are 7:00PM-8:30PM

*Court referral form, photo ID, case number, and appropriate court room attire required.
*Must not arrive under the influence alcohol, marijuana, or other drugs * Strictly enforced by law enforcement.
*Must not arrive with the odor of alcohol or marijuana on your person.
*Maintaining receipt of payment and attendance is your responsibility*This is your proof of compliance. (30.00 replacement fee.)
*No children under the age of 10 /em/ ted.
*Juvenile referrals must be accompanied by a parent or adult guardian.
*No one admitted after the class begins.

STOP DUI _____ Date 12/22/2021

AWARDS TO

# Rebeka Ojakhyan

FOR COMPLETING THE

# DUI Class

PRESENTED BY: _____ ON December 9, 2021

Mary McCrea Leonard, SW, MAJ, Director

[redacted]

| Section 6: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | X |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | X |

| Section 7: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration? | | X |
| 2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state even if the case or charge has been dismissed, sealed, acquitted, or expunged? | | X |
| 3. Have you been the subject of a board citation or administrative action whether completed or pending in <u>any</u> state? | | X |
| 4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state? | | X |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 7 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event MUST be provided.</u>**

**This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| **Reason/Charge** | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| **Name of Business/Industry/Entity** | | | | |

**Provide explanation below:**

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

| Section 8: You MUST submit the documents below with your application base on your qualifications as a PT. | |
|---|---|
| **Select your qualification as a PT (please check a box).** | **Required documents to be submitted with your application.** |
| ☐ The successful completion of an ASHP-approved PT school or training program | a. Provide a copy of the certification of completion of the program. |
| ☐ **Active practice in good standing** in another state as a PT, and the successful completion of at least 1,500 hours of employment as a PT in a pharmacy in that state performing the duties set forth in paragraph (c) of subsection 3 of NRS 639.1371, which must be verified by a **signed affidavit** by the managing pharmacist of the pharmacy. | a. Provide a copy of your PT registration, license, or certificate (if it is a requirement by that state to practice as a PT), which must be current, active, and in good standing.<br>b. Provide the signed affidavit from your managing pharmacist that you have completed at least 1,500 hours of employment as a PT in a pharmacy **in that state** (see form provided in this application). |
| ☐ The successful completion of at least 1,500 hours of training and experience as a registered pharmaceutical technician in training (PTT), performing the duties set forth in paragraph (c) of subsection 3 of NRS 639.1371, in Nevada licensed pharmacies, which must be verified by the managing pharmacist of the pharmacy. | a. Provide the signed form from your managing pharmacist that you have completed 1,500 hours of training and experience in a pharmacy **in this state** as a registered PTT (see form provided in this application). |
| ☐ The successful completion of a pharmaceutical technician training program conducted by a branch of the U.S. Armed Forces, the Indian Health Service of United States Department of Health and Human Services or the U.S. Department of Veterans Affairs. | a. Provide a copy of the certification of completion of the program. |

**Section 9: Fingerprints for a background check. ALL APPLICANTS MUST COMPLETE THIS SECTION. NRS 639.1371**

**In addition to the requirements in section 7, submit fingerprints for a background check** by following the instructions https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/FP%20Instructions%20NRS%20639.127%20639.1371.pdf

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I understand that Nevada law requires a registered pharmaceutical technician who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Rebeka Ojakhyan
Print Name

Original Signature, no copies or stamps accepted

1/31/23
Date

| Board Use Only | Date Received: 3-20-23 | Amount: 50.00 cc |
|---|---|---|

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Nevada Managing Pharmacist Certification of Training Hours for Pharmaceutical Technician in Training (PTT)

Rev (06/22/2022)

This form cannot be returned by fax or email.
We must have an original signature and fee to process.

**Section 1: Certification of PTT (NAC 639.242) MUST BE COMPLETED BY THE PHARMACY MANAGER**

Name of PTT: Rebeka Ojakhyan
PTT License #: PT26134
Pharmacy Manager Name: Sam Wu
Pharmacy Manager License #: 23059
Name of Pharmacy: Walgreens
Pharmacy License #: PH02371
Pharmacy Address: 8595 W. Warm Springs
City: Las Vegas
State: NV
Zip: 89113
Time period PTT employed (mm/yy-mm/yy): 11/21 — 01/23

I certify to the Board that the above-named PTT has successfully completed 1500 hours of training and experience performing the tasks of a PT listed in NRS 639.1371 (3)(c) and NAC 639.245(2). The specific training and experience completed is listed below:

ASHP Pharmacy Training Program, on-hand training — order entry, insurance billing, calculations, filling, inventory control.

Do you certify that the PTT is competent to perform the duties of a pharmaceutical technician? ☑Yes ☐No (If you answered "No" please explain why below):

I certify under penalty of perjury that the information contained on this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this form and any portion thereof is a public record unless otherwise declared confidential by law, and may be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020.

Sam Wu
Print Name (First, Last)

Original Signature of Managing Pharmacist, no copies or stamps accepted

1/31/23
Date

| Board Use Only | Date Received: 3-20-23 |
|---|---|

# PHARMACY TECHNICIAN CERTIFICATION BOARD

*certifies that*

## Rebeka Ojakhyan

has met all requirements for certification and merits the designation of

**Certified Pharmacy Technician (CPhT)**

| Certification Number | Initial Certification Date | Application Deadline | Expiration Date |
|---|---|---|---|
| 30219695 | December 19, 2022 | December 01, 2024 | December 31, 2024 |

PTCB
Pharmacy Technician Certification Board®

emilyhaugh
President, Certification Council

William Schmidt
Executive Director, CEO

Verify certification at **ptcb.org**.

# 5

| ANNUAL DISCIPLINE CASES<br>Reporting Period: January – July 2023 | | | |
|---|---|---|---|
| FINDING | HARM | DISCIPLINE INDIVIDUAL | DISCIPLINE FACILITY |
| YE failed to recognize the incorrect filling of the prescription upon data entry and final verification resulting in the sale of the prescription and failed to provide counseling to patient. | N/A | Fined $1,000.00; assessed $500.00 in attorney's fees and costs. | CVS fined $2,000.00; assessed $1,000.00 in attorney's fees and costs. |
| AV made false representation(s) to the Board in two of her PTT applications submitted to the Board. | N/A | Revoked two years; $358.36 in attorney's fees and costs. | N/A |
| JLW prescribed controlled substances to Nevada patients during the period where his controlled substance registration was expired. | N/A | Fined $5,000.00 and $500.00 in attorney's fees and costs. | N/A |
| JG: NSBME imposed discipline on JG's license to practice medicine for allowing unlicensed persons to act under his authority to unlawfully operate Image Med Spa and to access, possess, administer, dispense, and/or prescribe dangerous drugs and hypodermic devices to perform cosmetic injections and topical administration of dangerous drugs onsite to patients who had not been examined by a practitioner and without direct practitioner supervision. Some of the drug products and devices purchased are intended for distribution in foreign markets and are not approved for marketing, distribution or use in the U.S. | N/A | Fined $5,000.00; assessed $1,000.00 in recoverable attorney's fees and costs. | N/A |
| MR: NSBME placed MR's license to practice medicine on probation for engaging in conduct in violation of standards of practice related to writing prescriptions for controlled substances. | N/A | 2 year suspension; suspension is stayed and MR is placed on probation; fined $5,000.00; $1,000.00 in attorney's fees and costs; establish policies | N/A |

| ANNUAL DISCIPLINE CASES<br>Reporting Period: January – July 2023 | | | |
|---|---|---|---|
| FINDING | HARM | DISCIPLINE INDIVIDUAL | DISCIPLINE FACILITY |
| | | and procedures related to controlled substance prescriptions issued for the treatment of acute or chronic pain. | |
| DL disciplined by the NSBME on DL's license to practice medicine for failure to maintain medical records related to prescribing controlled substances. | N/A | 1 year suspension; suspension is stayed; fined $2,000.00; $500.00 attorney's fees and costs; establish policies and procedures to ensure that any controlled substance prescription complies with all applicable federal and state statutes and regulations. | N/A |
| JS surrendered her NSBME to practice medicine and no longer qualifies for a controlled substance registration. | N/A | Revoked 1 year. | N/A |
| ES stipulated to responsibility, and the CA Board disciplined ES for violations related to compounding pharmacy regulations. | N/A | 5 hours CE in pharmacy operations and pharmacy law and 5 hours CE in USP 797 in addition to CEs required for renewal; not own, have any legal or beneficial interest nor serve as manager, administrator, trustee, associate, or partner of any pharmacy and/or business licensed by the Board for 3; not compound any drugs that are intended to/or result in the shipment into Nevada for 3 years; assessed $750.00 in attorney's fees and costs. | N/A |

| ANNUAL DISCIPLINE CASES<br>Reporting Period: January – July 2023 | | | |
|---|---|---|---|
| FINDING | HARM | DISCIPLINE INDIVIDUAL | DISCIPLINE FACILITY |
| HM diverted controlled substances for personal use from his employer. | N/A | Revoked; fined $5,000; assessed $500 in recoverable attorney's fees and costs. | N/A |
| JLS failed to disclose that she was subject to a Board citation or administrative action on her pharmaceutical technician-in-training application. | N/A | Revoked; fined $5,000; assessed $446.23 in recoverable attorney's fees and costs. | N/A |
| Z, Inc. failed to disclose that they were subject to a Board citation or administrative action on their renewal pharmacy application. | N/A | Fined $5,000.00; assessed $500.00 in recoverable attorney's fees and costs. | N/A |
| GT surrendered her DEA Registration for Cause; unlawfully diverted and self-administered controlled substances during work hours. | N/A | Revoked; fined $5,000; assessed $1,000 in recoverable attorney's fees and costs; must submit an evaluation for substance use disorder and comply with any and all recommendations set forth by evaluation/ practitioner. | N/A |
| CH failed to disclose charges pending in US district court on his 2020 renewal application. | N/A | Fined $5,000; assessed $500 in recoverable attorney's fees and costs. | N/A |
| KMC, LLC appealed the Board's Findings of Fact, Conclusions of Law and Order filed on March 2, 2022. The case was remanded, and the Board heard the appeal on April 12, 2023. The Board found violations that the Respondent engaged in the business of furnishing medical devices in Nevada without a license. | N/A | KMC's license status is currently non-renewed. They may not engage in the business of furnishing medical devices in Nevada unless and until they apply for a license and appears before the Board to answer questions and give testimony regarding the application. | N/A |

| ANNUAL DISCIPLINE CASES<br>Reporting Period: January – July 2023 | | | |
|---|---|---|---|
| FINDING | HARM | DISCIPLINE INDIVIDUAL | DISCIPLINE FACILITY |
| CL's NSBVME license to practice veterinary medicine was suspended on December 12, 2022, for non-compliance with NSBVME orders entered in Case No. 06-2016DVM-21 arising from alcohol abuse. | N/A | Revoked 1 year; assessed $500.00 in recoverable attorney's fees and costs. | N/A |
| GW was convicted in June 2022, in *California vs. Gary Royce Wisner*, Sacramento County, California, Superior Court Case No. 18FE013037 on 10 felony counts of health care insurance fraud. | N/A | Revoked for 5 years; assessed $500.00 in recoverable attorney's fees and costs. | N/A |
| RF: NSBME imposed discipline on his license to practice medicine for engaging in conduct in violation of the standards of practice established by the NSBME related to prescribing controlled substances. | N/A | RF's CS registration is suspended for a period of 2 years. The suspension is stayed and RF is placed on probation;fined $5,000.00; assessed $500.00 in recoverable attorney's fees and costs. | N/A |
| RZ prescribed controlled substances to Nevada patients during the period where his controlled substance registration was non-renewed. | N/A | Fined $5,000.00. | N/A |
| SG prescribed controlled substances to Nevada patients during the period where her controlled substance registration was expired. | N/A | Fined $5,000.00; $500.00 in recoverable attorney's fees and costs. | N/A |
| CC prescribed controlled substances to Nevada patients during the period where her controlled substance registration was expired. | N/A | Fined $5,000.00; $500.00 in recoverable attorney's fees and costs. | N/A |
| EN failed to recognize the incorrect filling of the prescription upon data entry, verified and dispensed the incorrect dosage. He also failed to create a physical or | N/A | EN: fined $3,000.00; assessed $500.00 in recoverable attorney's fees and costs. | Fined $4,500.00; assessed $500.00 in recoverable attorney's fees and costs. |

| ANNUAL DISCIPLINE CASES<br>Reporting Period: January – July 2023 | | | |
|---|---|---|---|
| FINDING | HARM | DISCIPLINE INDIVIDUAL | DISCIPLINE FACILITY |
| electronic record of patient counseling or the refusal of patient counseling for the dispensing of the prescription.<br><br>CS failed to recognize the incorrect filling of the prescription upon data entry, verified and dispensed the incorrect dosage. | | CS: fined $1,500.00; assessed $500.00 in recoverable attorney's fees and costs. | |
| ES prescribed controlled substances to Nevada patients during the period that he did not hold a valid CS. | N/A | Fined $5,000.00; assessed $500.00 in recoverable attorney's fees and costs. | N/A |
| KN, CM, TT verified a final product as accurate when it was not, failed to contact the prescriber to clarify potential duplication errors, overrode Drug Utilization Review alerts and/or erroneously dispensed medication. | N/A | Fined $1,000.00 per Respondent. | WG fined $10,000.00; assessed $5,137.00 in recoverable attorney's fees and costs. |
| DE disciplined for violations related to failure to place a fill sticker on the back of the original hard-copy of a prescription resulting in duplicate prescriptions. | N/A | Fined $1,000.00; assessed $500.00 in recoverable attorney's fees and costs. | WG fined $2,000.00; assessed $1,000.00 in recoverable attorney's fees and costs. |
| MN disciplined for failure to place a fill sticker on the back of the original hard-copy of a prescription; engaged in unprofessional conduct when he performed data entry review and final verification and failed to identify that the patient had already received three fills prescribed on her patient profile; failed to segregate and/or dispose of adulterated and/or expired drugs in the pharmacy's inventory; misrepresented to the Board inspector that all adulterated and/or expired | N/A | Revoked. The revocation is stayed and MN is placed on probation for 2 years; fined $5,000.00; assessed $1,000.00 in recoverable attorney's fees and costs. Respondent currently owns a pharmacy and serves as the managing pharmacist. That pharmacy will be subject to quarterly unannounced inspections at the Respondent's expense. | WG fined $2,000.00; assessed $1,000.00 in recoverable attorney's fees and costs. |

| ANNUAL DISCIPLINE CASES<br>Reporting Period: January – July 2023 | | | |
|---|---|---|---|
| FINDING | HARM | DISCIPLINE INDIVIDUAL | DISCIPLINE FACILITY |
| drugs in the pharmacy's inventory had been segregated and/or disposed of. | | | |
| VB disciplined for violations related to prescribing of controlled substances and review of prescriber activity through the PMP. | N/A | Fined $5,000.00; assessed $500.00 in recoverable attorney's fees and costs. | N/A |
| CT disciplined for violations related to failure to enter prescription data correctly and filled a prescription written for trazodone with tramadol. | N/A | Fined $1,000.00; assessed $500.00 in recoverable attorney's fees and costs. | N/A |
| MC prescribed controlled substances to Nevada patients during the period where her CS registration was expired. | N/A | Fined $5,000.00 and $500.00 in recoverable attorney's fees and costs. | N/A |
| WR permitted an employee or staff member to access and utilize his secondary hard token authenticator and/or provided log-on information to his staff member with instructions to e-prescribe prescriptions. | N/A | Fined $4,000.00, $500.00 in recoverable attorney's fees and costs and 2 hours of CE, in addition to any medical CE required, regarding prescribing controlled substances. | N/A |
| JS permitted staff members not licensed as practitioners in Nevada to regularly use his credentials and act under his authority to issue electronic prescriptions for controlled substances. He failed to review his prescriber activity in the PMP between September 23, 2016, and August 13, 2022, and permitted staff members to access the PMP using his credentials; failed to verify the accuracy of dispensed prescriptions and to initial each prescription. | N/A | JS' CS and PD registrations are suspended for 1 year. The suspensions are stayed and he is placed on probation. Fined $10,000.00 and $5,363.00 in recoverable attorney's fees and costs; establish and put into practice policies and procedures to ensure that any prescription complies with the provisions of federal and state law, shall be subject to quarterly PMP | N/A |

| ANNUAL DISCIPLINE CASES<br>Reporting Period: January – July 2023 | | | |
|---|---|---|---|
| FINDING | HARM | DISCIPLINE INDIVIDUAL | DISCIPLINE FACILITY |
| | | compliance checks, and quarterly inspections by Board staff at Respondent's expense. | |
| RC permitted unlicensed staff to access and/or possess controlled substances and/or dangerous drugs, failure to maintain effective security controls by allowing unregistered persons key access to controlled substances and/or dangerous drugs, failure to issue a written prescription for each medication dispensed, failed to verify medications for accuracy prior to dispensing, failure to maintain complete, accurate and readily retrievable records of all controlled substances and/or dangerous drugs purchased and dispensed, failure to inventory controlled substances at least once every 2 years, failure to properly store and maintain the inventory, failure to segregate and/or dispose of adulterated and/or expired dangerous drugs, possessed pre-drawn, unlabeled syringes containing unidentified dangerous drugs. | N/A | RC's CS and PD registrations are suspended the; suspension is stayed, and RC placed on probation for a period of one year. During the probationary period, his dispensing practice shall undergo 2 inspections by the Board at his expense. Update policies and procedures withing 6 months; fined $5,000.00 and $1,000.00 in recoverable attorney's fees and costs. | N/A |
| LH unlawfully authorized dispensation of medications to patients when she was not present, failure to maintain effective security controls by allowing unregistered persons key access to controlled substances and/or dangerous drugs, failure to issue a written prescription for each | N/A | LH's CS and PD registrations are suspended the; suspension is stayed, and LH placed on probation for a period of one year. During the probationary period, her dispensing practice shall undergo 2 inspections | N/A |

| ANNUAL DISCIPLINE CASES<br>Reporting Period: January – July 2023 | | | |
|---|---|---|---|
| FINDING | HARM | DISCIPLINE INDIVIDUAL | DISCIPLINE FACILITY |
| medication dispensed, failure to verify medications for accuracy prior to dispensing, failure to maintain complete, accurate and readily retrievable records of all controlled substances and/or dangerous drugs purchased and dispensed, failure to inventory controlled substances at least once every 2 years, failure to properly store and maintain the inventory, and failure to segregate and/or dispose of adulterated and/or expired dangerous drugs, possessed pre-drawn, unlabeled syringes containing unidentified dangerous drugs. | | by the Board at her expense. Update policies and procedures withing 6 months; fined $2,500.00 and $1,000.00 in recoverable attorney's fees and costs. | |
| Smith's Pharmacy #389 operated without a managing pharmacist during August 12, 2022, to September 1, 2022. | N/A | N/A | Fined $5,000; assessed $500 in recoverable attorney's fees and costs. |
| JD as managing pharmacist is responsible for a dispensing error caused by pharmacy employees. | N/A | Fined $3,000; assessed $500.00 in recoverable attorney's fees and costs. | Fined $4,000; assessed $952.60 in recoverable attorney's fees and costs. |
| BR engaged in the sale of veterinary drugs prior to the issuance of a Nevada Veterinary Drug Supplier License which they were served cease and desist/citation. BR appealed the citation. | N/A | N/A | The Board upheld the $5,000 fine. |

# 5A

FILED
FEB 06 2023
NEVADA STATE BOARD OF PHARMACY

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

| | |
|---|---|
| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br>**v.**<br><br>**WALGREENS PHARMACY #4854,**<br>**Pharmacy License No. PH01293,**<br><br>**MINHQUANG D. NGUYEN, RPH,**<br>**Certificate of Registration No. 15913,**<br><br>**DIMITRIS EFSTATHIOU, RPH,**<br>**Certificate of Registration No. 17277, and**<br><br>**MARIA CRUZ, RPH,**<br>**Certificate of Registration No. 18166,**<br><br>**Respondents.** | **CASE NOS. 18-021-PH-S**<br>**18-021-RPH-A-S**<br>**18-021-RPH-C-S**<br>**18-021-RPH-D-S**<br><br>**FIRST AMENDED**<br>**NOTICE OF INTENDED ACTION**<br>**AND ACCUSATION** |

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

## JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Minhquang D. Nguyen, RPh (Nguyen), Certificate of Registration No. 15913, Respondent Dimitris Efstathiou, RPh (Efstathiou), Certificate of Registration No. 17277, and Respondent Maria Cruz, RPh (Cruz), Certificate of Registration No. 18166, were pharmacists registered with the Board, and Respondent Walgreens Pharmacy #4854, Pharmacy License No. PH01293, was a pharmacy licensed by the Board.

2. Nguyen was previously subject to discipline in case nos. 13-006-RPH-S and18-055-RPH-A-S, and currently a named respondent in case no. 19-100-RPH-S.

## FACTUAL ALLEGATIONS

3. Nguyen was employed as managing pharmacist and Efstathiou and Cruz were employed as staff pharmacists by Walgreens Pharmacy #4854 at the time of the events alleged herein.

4. On or about October 7, 2017, Dr. C.C. wrote three (3) separate prescriptions for patient L.S. for Adderall, 30 mg tablets, quantity 90 tablets, with instructions to take 1 tablet three times per day. The first prescription was for immediate fill, the second prescription stated, "Do not fill before 11/7/2017", and the third prescription stated, "Do not fill before 12/7/2017".

5. On or about October 9, 2017, all three prescriptions were presented by patient L.S. to Walgreens Pharmacy #4854 and scanned into the computer system.

6. The first prescription was designated prescription no. 1850877 and subsequently processed, filled, and dispensed to patient L.S. on or about October I1, 2017.

7. The prescription post-dated 11/07/2017 was designated prescription no. 1863870 and placed on hold; however, the prescription number was not written on the original hard copy of the prescription.

8. The prescription post-dated 12/07/2017 was designated prescription no. 1896898 and placed on hold; however, the prescription number was not written on the original hard copy of the prescription.

9. On or about October 14, 2017, the original hard copy of the prescription post-dated 11/07/2017 was erroneously re-scanned and designated a second prescription no. 1874629, and the original hard copy of the prescription post-dated 12/07/2017 was erroneously re-scanned and designated a second prescription no. 1886042.

10. On or about November 18, 2017, prescription no. 1893870, post-dated 11/07/2017, was processed, filled and dispensed. Data entry review and final verification were

performed by Efstathiou, who failed to place a fill sticker on the back of the original hard copy of the prescription.

11. On or about December 24, 2017, prescription no. 1874629, post-dated 11/07/2017, was processed, filled and dispensed. Data entry review was performed by Cruz, who failed to identify the duplication with prescription no. 1863870.

12. On or about January 29, 2018, prescription no. 1886042, post-dated 12/07/2017, was processed, filled and dispensed. Data entry review and final verification were performed by Nguyen, who failed to place a fill sticker on the back of the original hard copy of the prescription and failed to identify that patient L.S. had already received the three fills prescribed on her patient profile.

13. On or about February 28, 2018, prescription no. 1896898, post-dated 12/07/2017, was processed, filled and dispensed. Data entry review was performed by Cruz, who failed to identify the duplication with prescription no. 1886042.

**COUNT ONE**

**Recordkeeping Violations**

(Respondents Nguyen and Efstathiou)

14. Prescription records must be maintained in pertinent part in conformance with NRS 639.236, NAC 639.706 and/or NAC 639.910.

15. By failing to place a fill sticker on the back of the original hard copy of the prescription when filling prescription no. 1893870, Efstathiou violated NRS 639.236(2) and is subject to discipline pursuant to NRS 639.210(12). By failing to place a fill sticker on the back of the original hard copy of the prescription when filling prescription no. 1886042, Nguyen violated NRS 639.236(2) and is subject to discipline pursuant to NRS 639.210(12).

## COUNT TWO

**Failure to Identify Duplicate Dispensed Medication/Unprofessional Conduct**

(Respondents Nguyen and Cruz)

16. Unprofessional conduct includes the failure by a licensee to follow strictly the instructions of a practitioner when filling, labeling, and dispensing a prescription. NAC 639.945(1)(d). It also includes a licensee performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

17. Nguyen engaged in unprofessional conduct as defined in NAC 639.945(1)(d) and (i) when she performed data entry review and final verification on prescription no. 1886042 and failed to identify that patient L.S. had already received the three fills prescribed on her patient profile. Nguyen is therefore subject to discipline pursuant to NRS 639.210(4).

18. Cruz engaged in unprofessional conduct as defined in NAC 639.945(1)(d) and (i) when she performed data entry review on prescription no. 1874629 and failed to identify the duplication with prescription no. 1863870, and again when she performed data entry review on prescription no. 1896898 and failed to identify the duplication with prescription no. 1886042. Cruz is therefore subject to discipline pursuant to NRS 639.210(4).

## COUNT THREE

**Managing Pharmacist Responsibility**

(Respondent Nguyen)

19. As the managing pharmacist of Walgreens Pharmacy #4854 at the time of the violations alleged herein, including the failure to note the prescription number on the original hard copy of prescriptions, in violation of NRS 639.236, NAC 639.706 and/or NAC 639.910, resulting in the duplicate prescriptions, Nguyen is responsible for those violations and subject to discipline pursuant to NRS 639.210(12) and (15), NRS 639.220(1) and/or NAC 639.702.

**COUNT FOUR**
**Pharmacy/Pharmacy Owner Responsibility**
(Respondent Walgreens Pharmacy #4854)

20. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

21. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Walgreens Pharmacy #4854 is responsible for those violations, including all errors and omissions of Nguyen, Efstathiou and Cruz, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(2).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license, and certificates of registrations of these Respondents.

Signed this 6th day of February 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

## NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**MARIA CRUZ, RPH,**<br>**Certificate of Registration No. 18166,**<br><br>**Respondent.** | **CASE NO. 18-021-RPH-D-S**<br><br>**STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING** |

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, March 8, 2023, at 9:00 AM PST or soon thereafter at the following location:**

**Hilton Garden Inn Las Vegas Strip South**
**7830 S. Las Vegas Blvd.**
**Las Vegas, NV 89123**

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 6th day of February 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

# CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 6th day of February 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Walgreens Pharmacy #04854
4771 W. Craig Rd.
North Las Vegas, NV 89032

Minhquang D. Nguyen, R.Ph.
[redacted] Alpine Lily Dr.
Las Vegas, NV 89141

Minhquang D. Nguyen, R.Ph.
[redacted] W. Spring Mountain Rd. #A
Las Vegas, NV 89146

Dimitris Efstathiou, R.Ph.
[redacted] Promontory Dr.
Henderson, NV 89014

Maria Cruz, R.Ph.
[redacted] Cortina Rancho St.
Las Vegas, NV 89147

Maria Cruz, R.Ph.
[redacted] W. Craig Rd.
North Las Vegas, NV 89032

William Stilling, Esq.
222 South Main Street, Suite 500
Salt Lake City, Utah 84101

Darlene Nases
DARLENE NASES

FILED
MAY 31 2023
NEVADA STATE BOARD
OF PHARMACY

William J. Stilling (NBN 9915)
STILLING & HARRISON, PLLC
222 S. Main St., Ste. 500
Salt Lake City, Utah 84101
Telephone: 801-980-1888
Facsimile: (801) 341-2021
Email: bstilling@SHhealthlawyers.com

Attorneys for Respondents

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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|---|---|
| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**WALGREENS PHARMACY #4854, Pharmacy License No. PH01293,**<br><br>**MINHQUANG D. NGUYEN, RPH, Certificate of Registration No. 15913, and**<br><br>**DIMITRIS EFSTATHIOU, RPH, Certificate of Registration No. 17277,**<br><br>**MARIA CRUZ, RPH, Certificate of Registration No. 18166,**<br><br>**Respondents.** | **CASE NOS. 18-021-PH-S**<br>**18-021-RPH-A-S**<br>**18-021-RPH-B-S**<br>**18-021-RPH-C-S**<br>**18-021-RPH-D-S**<br><br>**RESPONDENTS' ANSWER AND NOTICE OF DEFENSE** |

Respondents Walgreens Pharmacy #4854, 5814, Minhquang D. Nguyen, RPh, Dimitris Efstathiou, RPh, , and Maria Cruz, RPh by and through their counsel William J. Stilling, of and for Stilling & Harrison, PLLC, answer and provide notice of their defense to the Notice of Intended Action and Accusation ("Notice") in the above-entitled matter and declare as follows.

## REQUEST FOR HEARING

Respondents request a hearing on the Notice.

## RESPONSES TO ALLEGATIONS AND CAUSES OF ACTION

In answer to the Notice, Respondents admit, deny, and allege as follows:

## JURISDICTION

1. Respondents admit the allegations in paragraph 1.

2. Respondents admit the allegations in paragraph 2.

## FACTUAL ALLEGATIONS

3. Respondents admit the allegations in paragraph 3.

4. Respondents lack sufficient knowledge to admit or deny the allegations in paragraph 4 and therefore deny the same.

5. Respondents admit the allegations in paragraph 5.

6. Respondents admit the allegations in paragraph 6.

7. Respondents admit the allegations in paragraph 7.

8. Respondents admit the allegations in paragraph 8.

9. Respondents admit the allegations in paragraph 9.

10. Respondents admit the allegations in paragraph 10.

11. Respondents admit that on or about December 24, 2017, prescription no. 1874629, post-dated 11/07/2017, was processed, filled and dispensed and that data entry review was performed by Cruz. However, there was nothing on the prescription 1874629 to indicate that it had been previously filled. Respondents deny all remaining allegations in paragraph 11.

12. Respondents admit that: (i) on or about January 29, 2018, prescription no. 1886042, post-dated 12/07/2017, was processed, filled and dispensed; (ii) data entry review and final verification were performed by Nguyen who did not place a fill sticker on the back of the original hard copy of the prescription. Respondents deny all remaining allegations in paragraph 12.

13. Respondents admit that: (i) on or about February 28, 2018, prescription no. 1896898, post-dated 12/07/2017, was processed, filled and dispensed and (ii) data entry review was performed by Cruz. However, there would have been nothing on the prescription 1896898 to indicate that it had been previously filled. Respondents deny all remaining allegations in paragraph

**COUNT ONE**
**Recordkeeping Violations**
(Respondents Nguyen and Efstathiou)

14. Paragraph 14 is a statement of law and is not susceptible to admission or denial. To the extent that paragraph 14 implies any unprofessional or unlawful conduct, Respondents deny the same.

15. Respondents deny the allegations in paragraph 15.

**COUNT TWO**
**Failure to Identify Duplicate Dispensed Medication/Unprofessional Conduct**
(Respondents Nguyen and Cruz)

16. Paragraph 16 is a statement of law and is not susceptible to admission or denial. To the extent that paragraph 16 implies any unprofessional or unlawful conduct, Respondents deny the same.

17. Respondents deny the allegations in paragraph 17.

18. Respondents deny the allegations in paragraph 18.

**COUNT THREE**
**Managing Pharmacist Responsibility**
(Respondent Nguyen)

19. Respondents deny the allegations in paragraph 19.

**COUNT FOUR**
**Pharmacy/Pharmacy Owner Responsibility**
(Respondent Walgreens Pharmacy #4854)

20. Paragraph 20 is a statement of law and is not susceptible to admission or denial. To the extent that paragraph 20 implies any unprofessional or unlawful conduct, Respondents deny the same.

21. Respondents deny the allegations in paragraph 21.

**RESERVATION OF RIGHTS, DEFENSES, AND GENERAL DENIAL**

22. Each Count fails to state a claim upon which relief can be granted.

23. To the extent Respondents did not specifically admit allegations in the Notice, they deny such allegations.

24. Sanctioning Respondent Maria Cruz would be unfair and unjust in light of her circumstances. Maria Cruz retired March 2021. She now lives in the Philippines. She no longer has a pharmacy license and never intends to practice pharmacy again. Her decision to retire had nothing to do with this case. Ms. Cruz has never been sanctioned for any act or omission during her eleven years of practice in Nevada or anywhere else. Maria Cruz recognizes that the Board needs to be consistent in its decisions. But some cases are different and require wise use of discretion as fairness requires. This is such a case. If the Board agrees to dismiss the claims against Maria Cruz, it would not set a precedent that a pharmacist can escape sanctions by retiring. Rather, a decision to dismiss the claims against her or to forego any sanctions would simply recognize that it is fair not to impose sanctions on a pharmacist who retires some three years after an alleged violation and before any Notice of Intended Action is filed, who moves back to her native country, and who has never before been sanctioned by a board of pharmacy. Ms. Cruz did not act unprofessionally or unlawfully because she had no reason to believe there was a duplicate of the prescription she was filling as described in paragraphs 11 and 13. Even if this Board finds that Maria Cruz engaged in

unprofessional conduct, it should not impose sanctions. Just because a government body has the power to do something does not necessarily mean that it should do so—especially when fairness dictates otherwise.

## PRAYER FOR RELIEF

25. Respondents pray for the following relief:

a. That the Notice be dismissed or that the Board finds that the allegations in the Notice and all evidence presented to the Board do not support imposing discipline on any of the Respondents.

b. That the Board dismiss all Causes of Acton in in the Notice.

c. That the Board provide further relief to Respondents as it finds just and proper.

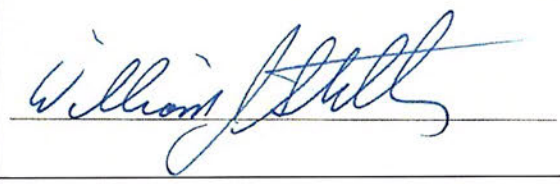
DATED this 31st day of May 2023.



William J. Stilling
STILLING & HARRISON, PLLC.
Attorneys for Respondents

## CERTIFICATE OF SERVICE

I hereby certify that on May 31, 2023, I caused to be served a true and correct copy of the foregoing **ANSWER AND NOTICE OF DEFENSE** by the method indicated below to:

| | | |
|---|---|---|
| Brett Kandt<br>General Counsel<br>Nevada State Board of Pharmacy<br>1985 Damonte Ranch Pkwy #206,<br>Reno, NV 895219<br>bkandt@pharmacy.nv.gov | | ☐ U.S. Mail postage prepaid<br>☐ Hand delivery<br>☐ Overnight Mail<br>☐ Facsimile<br>☑ Electronic Mail |
| David Wuest<br>Executive Secretary<br>Nevada State Board of Pharmacy<br>985 Damonte Ranch Pkwy #206,<br>Reno, NV 895219<br>dwuest@pharmacy.nv.gov | | ☐ U.S. Mail postage prepaid<br>☐ Hand delivery<br>☐ Overnight Mail<br>☐ Facsimile<br>☑ Electronic Mail |
| Yenh Long<br>Deputy Executive Secretary<br>Nevada State Board of Pharmacy<br>985 Damonte Ranch Pkwy #206,<br>Reno, NV 895219<br>ylong@pharmacy.nv.gov | | ☐ U.S. Mail postage prepaid<br>☐ Hand delivery<br>☐ Overnight Mail<br>☐ Facsimile<br>☑ Electronic Mail |
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FILED
JUN 29 2023
NEVADA STATE BOARD OF PHARMACY

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**ROOSEVELT WATSON, MD, Certificate of Registration No. CS12287,**<br><br>**Respondent.** | **CASE NO. 22-112-CS-S**<br><br>**NOTICE OF INTENDED ACTION AND ACCUSATION** |

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

## JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Roosevelt Watson, MD, held a Nevada controlled substance registration, Certificate of Registration No. CS12287, issued by the Board.

## FACTUAL ALLEGATIONS

2. From March 2022 to March 2023, Respondent issued 119 controlled substance prescriptions for 6 family members with whom Respondent had not established a bona fide therapeutic relationship, for whom Respondent had neither diagnosed nor determined that a controlled substance was medically necessary, and without reviewing each patient's utilization report in the Prescription Monitoring Program (PMP) database.

3. On or about October 31, 2022, Respondent surrendered his Registration No. FW4079427 to the Drug Enforcement Administration by executing a DEA Form 104 – "Voluntary Surrender of Controlled Substance Privileges."

4. On or about January 25, 2023, Board staff served Respondent with notice that the surrender of his DEA Registration No. FW4079427 operates as an immediate suspension of his Certificate of Registration No. CS12287 with the Board pursuant to NRS 639.2107, and that Respondent must immediately cease and desist possessing, administering and/or prescribing controlled substances for Nevada patients.

## APPLICABLE LAW

5. A prescription for a controlled substance may be issued only for a legitimate medical purpose and after review of a patient's utilization report in the Prescription Monitoring Program (PMP) database in conformance with NRS 639.23507. 21 CFR § 1306.04(a); NRS 453.381(1).

6. Conspiring to violate the Controlled Substances Act is a felony offense. 21 U.S.C. § 846; NRS 453.401(l)(a).

7. A practitioner must hold a license to practice his or her profession in this State and be registered with both the DEA and the Board to possess, administer, prescribe and/or otherwise dispense any controlled substance. NRS 453.226(1); 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03.

8. The surrender, revocation or a suspension that has not been stayed of any registration of a practitioner by the DEA operates as an immediate suspension of a registration issued by the Board pursuant to NRS 453.226. NRS 639.2107.

9. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

10. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct

contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

11. Prescribing a drug to any patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(o) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

12. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

13. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

14. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest, or upon a finding that the registrant no longer possesses his or her federal registration to dispense controlled substances and is no longer authorized by federal law to dispense those substances. NRS 453.236(1)(d) and NRS 453.241(1).

## COUNT ONE

### Violation of Federal Controlled Substances Act

15. By issuing 119 controlled substance prescriptions for 6 family members with whom Respondent had not established a bona fide therapeutic relationship, for whom Respondent had neither diagnosed nor determined that a controlled substance was medically necessary, and without reviewing each patient's utilization report in the Prescription Monitoring Program (PMP) database, Respondent violated, attempted to violate, assisted or abetted in the

violation of or conspired to violate 21 U.S.C. § 846 and/or 21 CFR § 1306.04(a), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11).

**COUNT TWO**
**Violation of State Law**

16. By issuing 119 controlled substance prescriptions for 6 family members with whom Respondent had not established a bona fide therapeutic relationship, for whom Respondent had neither diagnosed nor determined that a controlled substance was medically necessary, and without reviewing each patient's utilization report in the Prescription Monitoring Program (PMP) database, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.381(1), NRS 453.401(1)(a) and/or NRS 639.23507, and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b).

**COUNT THREE**
**Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction**

17. By issuing 119 controlled substance prescriptions for 6 family members with whom Respondent had not established a bona fide therapeutic relationship, for whom Respondent had neither diagnosed nor determined that a controlled substance was medically necessary, and without reviewing each patient's utilization report in the Prescription Monitoring Program (PMP) database, Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

**COUNT FOUR**
**Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties**

18. By his acts as alleged herein, Respondent has performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC

639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), and/or NRS 639.210(4).

**COUNT FIVE**

**Unprofessional Conduct – Prescribing Without Bona Fide Therapeutic Relationship**

19. By unlawfully prescribing controlled substances to patients with whom he did not have a bona fide therapeutic relationship as alleged in paragraph 2 herein, Respondent engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(o), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

**COUNT SIX**

**Commission of Acts that Render Registration Inconsistent with the Public Interest**

20. By his acts as alleged herein, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

**COUNT SEVEN**

**Surrender of DEA Registration**

21. By the surrender of his DEA Registration No. FW4079427, Respondent no longer qualifies for registration to dispense controlled substances under federal or state law and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

22. The pre-hearing suspension of Respondent's Certificate of Registration No. CS12287 pursuant to NRS 233B.127(3), NRS 453.241(3) and/or NRS 639.2107 is subject to review by the Board. *Barry v. Barchi*, 443 U.S. 55, 99 S. Ct. 2642 (1979); *Spiegel v. Ryan*, 946 F.2d 1435, 1439 (9th Cir. 1991).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 29th day of JUNE 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

## NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

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| NEVADA STATE BOARD OF PHARMACY,<br><br>Petitioner,<br><br>v.<br><br>ROOSEVELT WATSON, MD,<br>Certificate of Registration No. CS12287,<br><br>Respondent. | Case No. 22-112-CS-S<br><br>STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING |

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, September 6, 2023, at 9:00 AM PST or soon thereafter at the following location:**

**Hilton Garden Inn Las Vegas Strip South**
**7830 S. Las Vegas Blvd**
**Las Vegas, NV 89123**

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 29th day of JUNE, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**ROOSEVELT WATSON, MD,**<br>**Certificate of Registration No. CS12287,**<br><br>**Respondent.** | **Case No. 22-112-CS-S**<br><br>**ANSWER AND NOTICE OF DEFENSE** |

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

**ROOSEVELT WATSON, MD**

# CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 30th day of June, 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Roosevelt Watson, MD
6900 Pecos Rd.
NORTH LAS VEGAS, NV 89086

SHIRLEY HUNTING

JOE LOMBARDO
Governor

HELEN PARK
*President*

J. DAVID WUEST
*Executive Secretary*

**STATE OF NEVADA**

**BOARD OF PHARMACY**

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

January 25, 2023

**VIA CERTIFIED U.S. MAIL AND ELECTRONIC MAIL TO:**

roosevelt.watson@va.gov

Roosevelt Watson, MD
6900 Pecos Road
North Las Vegas NV 89086

***Re: Notice of Suspension of Registration No. CS12287 (Case No. 22-112-CS-S)***

Dear Dr. Watson:

The Nevada State Board of Pharmacy (Board) has been notified that you surrendered your DEA Registration No. FW4079427 on or about October 31, 2022 (copy enclosed). Please be advised that pursuant to NRS 639.2107 your surrender of your DEA Registration No. FW4079427 operates as an immediate suspension of your Certificate of Registration No. CS12287 with the Board.

You may not possess (except pursuant to the lawful order of a practitioner), administer, prescribe or dispense a controlled substance until you petition the Board for reinstatement pursuant to NRS 639.2565 and the Board reinstates your certificate of registration. Your PMP account is also suspended pursuant to NAC 453.078.

You may request a hearing before the Board to contest the suspension of your registration by submitting a written request to the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

Regards,

Brett Kandt
General Counsel
Nevada State Board of Pharmacy



9171 9690 0935 0279 7891 53

U. S. Department of Justice - Drug Enforcement Administration

# SURRENDER FOR CAUSE OF DEA CERTIFICATE OF REGISTRATION

DEA USE ONLY

File No.

In view of my alleged failure to comply with the Federal requirements pertaining to controlled substances or list 1 chemicals, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices on my part, I hereby surrender for cause my Drug Enforcement Administration (DEA) Certificate of Registration.

I understand that submission of this document to DEA, including any employee of DEA, shall result in the immediate termination of my registration.

I understand that I am not entitled to a refund of any payments made by me in connection with my registration.

I understand that, beginning on the date that I sign below, I am not authorized to order, manufacture, distribute, possess, dispense, administer, prescribe, or engage in any other activities with controlled substances or list I chemicals.

With the understanding that I am not required to surrender my DEA Certificate of Registration, I freely and under no duress, implied or expressed, execute this document and choose to take the action described herein.

| NAME OF REGISTRANT *(Print)* | ADDRESS OF REGISTRANT |
|---|---|
| Roosevelt Watson, M.D. | [redacted] S. Buffalo Drive<br>Las Vegas, NV 89113 |
| DEA REGISTRATION NO.<br>FW4079427 | |
| SIGNATURE OF REGISTRANT OR AUTHORIZED INDIVIDUAL<br>Roosevelt Watson | DATE<br>10/31/22 |

**WITNESSES TO REGISTRANT'S SIGNATURE**

| NAME AND DATE | TITLE |
|---|---|
| William J Coday 10-31-22 | Diversion Investigator |
| NAME AND DATE | TITLE |
| Cynthia R Hightower 10-31-22 | Diversion Group Supervisor |

**PRIVACY ACT**

**AUTHORITY:** Section 301 of the Controlled Substances Act of 1970 (21 U.S.C 821).
**PURPOSE:** Permit surrender for cause of DEA Certificate of Registration.
**ROUTINE USES:** The Controlled Substances Act Registration Records produce special reports as required for statistical analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:
A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
C. Persons registered under the Controlled Substances Act (21 U.S.C. 822 and 957) for the purpose of verifying the registration of customers and practitioners.
**EFFECT:** Submission of this information is voluntary. There is no effect on the individual if not provided.

# 5C

FILED
MAY 04 2023
NEVADA STATE BOARD OF PHARMACY

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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|---|---|
| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br>**v.**<br><br>**WALGREENS PHARMACY #6425, Pharmacy License No. PH01594, and**<br><br>**JUAN PEIDRA FLORES, RPH, Certificate of Registration No. 20887,**<br><br>**Respondents.** | **CASE NOS. 22-359-PH-S**<br>**22-359-RPH-S**<br><br>**FIRST AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION** |

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

## JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Juan Peidra Flores, RPh (Flores), Certificate of Registration No. 20887, was a pharmacist registered with the Board, and Respondent Walgreens Pharmacy #6425, Pharmacy License No. PH01594, was a pharmacy licensed by the Board.

## FACTUAL ALLEGATIONS

2. Flores was employed as managing pharmacist by Walgreens Pharmacy #6425 at the time of the events alleged herein.

3. On or about June 13, 2022, patient R.C. visited an urgent care facility experiencing a scalp rash and was prescribed hydrocortisone 2.5% crème containing propylene glycol.

4. On the same date R.C. presented the prescription to Walgreens Pharmacy #6425, where it was scanned into the computer system, designated prescription no. 1949022 and subsequently processed, filled, and dispensed to the patient by Flores.

5. In the process of dispensing prescription no. 1949022 Flores twice overrode drug utilization review (DUR) warnings noting that R.C. has an allergy to propylene glycol and failed to contact the prescriber for alternative medication.

6. Upon use of the medication R.C. experienced an allegoric reaction including hair loss.

## COUNT ONE

**Error in Dispensing Prescription/Unprofessional Conduct**
(Respondent Flores)

7. Unprofessional conduct includes the failure by a licensee to confer with the prescriber if there is an error or omission in it which should be questioned. NAC 639.945(1)(e). It also includes a licensee performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

8. Flores engaged in unprofessional conduct as defined in NAC 639.945(1)(e) and (i) when he twice overrode drug utilization review (DUR) warnings noting that R.C. has an allergy to propylene glycol and failed to contact the prescriber for alternative medication prior to dispensing prescription no. 1949022. Flores is therefore subject to discipline pursuant to NRS 639.210(4).

## COUNT TWO

**Pharmacy/Pharmacy Owner Responsibility**
(Respondent Walgreens Pharmacy #6425)

9. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

10. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondent Walgreens Pharmacy #6425 is responsible for those violations, including all errors and omissions of Flores, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(2).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration/licenses of these respondents.

DATED this 4th day of MAY, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

## NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the First Amended Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this First Amended Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**WALGREENS PHARMACY #6425,**<br>**Pharmacy License No. PH01594,**<br><br>**Respondent.** | **CASE NO. 22-359-PH-S**<br><br>**STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING** |

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a First Amended Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the First Amended Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the First Amended Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206; Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the First Amended Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, June 14, 2023, at 9:00 AM PST or soon thereafter at the following location:**

**Hilton Garden Inn Las Vegas Strip South**
**7830 S. Las Vegas Blvd**
**Las Vegas, NV 89123**

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 4th day of May, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**WALGREENS PHARMACY #6425,**<br>**Pharmacy License No. PH01594,**<br><br>**Respondent.** | **CASE NO. 22-359-PH-S**<br><br><br><br>**ANSWER AND NOTICE OF DEFENSE** |

Respondent above named, in answer to the First Amended Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the First Amended Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the First Amended Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

**TYPE OR PRINT NAME**

_____

**AUTHORIZED REPRESENTATIVE FOR WALGREENS PHARMACY #6425**

# CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 5th day of May 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Juan Peidra Flores, RPH
[redacted]Dalton Lake St.
Las Vegas, NV 89178

Walgreens Pharmacy #06425
900 N. Rancho Dr.
Las Vegas, NV 89106-1005

William Stilling, Esq.
222 South Main Street, Suite 500
Salt Lake City, Utah 84101

SHIRLEY HUNTING

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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|---|---|
| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br>**v.**<br><br>**WALGREENS PHARMACY #6425, Pharmacy License No. PH01594, and**<br><br>**JUAN PEIDRA FLORES, RPH, Certificate of Registration No. 20887,**<br><br>**Respondents.** | **CASE NOS. 22-359-PH-S**<br>**22-359-RPH-S**<br><br>**STIPULATION AND ORDER** |

Brett Kandt, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondent Juan Peidra Flores, RPh (Flores), Certificate of Registration No. 20887, and Respondent Walgreens Pharmacy #6425, Pharmacy License No. PH01594, jointly by and through counsel**,** William Stilling, Esq. of Stilling & Harrison, **HEREBY STIPULATE AND AGREE THAT**:

1. The Board has jurisdiction over Respondents and these matters.

2. On or about May 4, 2023, Board Staff served Respondents with the First Amended Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondents and Notice of Hearing.

3. Respondents jointly filed an Answer and Notice of Defense to the Accusation.

4. Respondents are aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering this Stipulation.

5. Respondents are aware of the right to a hearing on the matters alleged in the Accusation, their right to reconsideration, their right to appeal, and any and all other rights which may be accorded pursuant to NRS Chapter 233B, Nevada Administrative Procedure Act, NRS

Chapter 622A, Administrative Procedure Before Certain Regulatory Bodies, and NRS Chapter 639, Nevada Pharmacy Act.

6. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondents, or any of them, have failed to comply with the provisions of this Stipulation, Respondents hereby knowingly and voluntarily waive their rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to them by NRS Chapter 233B, Nevada Administrative Procedure Act, NRS Chapter 622A, Administrative Procedure Before Certain Regulatory Bodies, and NRS Chapter 639, Nevada Pharmacy Act.

7. Respondents admit that evidence exists, and that Board's staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in the Accusation, *to wit,* that:

A. Respondent Flores engaged in unprofessional conduct as defined in NAC 639.945(1)(e) and (i) when he twice overrode drug utilization review (DUR) warnings noting that R.C. has an allergy to propylene glycol and failed to contact the prescriber for alternative medication prior to dispensing prescription no. 1949022, resulting in patient harm and subjecting Flores to discipline pursuant to NRS 639.210(4).

B. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondent Walgreens Pharmacy #6425 is responsible for those violations, including all errors and omissions of Flores, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(2).

8. Those violations are plead with particularity in the Accusation and are grounds for action pursuant to NRS 639.210 and NRS 639.255.

9. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Juan Peidra Flores, RPh, Certificate of Registration No. 20887, stipulate to the following penalties:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent Flores shall pay a fine of One-Thousand Dollars ($1,000.00) for the violations; and

B. Pursuant to NRS 622.400, Respondent Flores shall pay Five-Hundred Dollars ($500.00) to partially reimburse the Board for recoverable attorney's fees and investigative costs.

10. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Walgreens Pharmacy #6425, Pharmacy License No. PH01594, stipulate to the following penalties:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent Walgreens Pharmacy #6425 shall pay a fine of Two-Thousand Dollars ($2,000.00) for the violations; and

B. Pursuant to NRS 622.400, Respondent Walgreens Pharmacy #6425 shall pay One-Thousand Dollars ($1,000.00) to partially reimburse the Board for recoverable attorney's fees and investigative costs.

11. Any failure by any Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing the non-compliant Respondent(s) to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by any Respondent, the Board may impose additional discipline upon the non-compliant Respondent(s) consistent with the provisions of NRS Chapter 639.

12. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 6, 2023.

Respondents will appear in person at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondents or counsel are not present at the meeting.

13. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60.

14. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board at a later date. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

15. Upon approval of this Stipulation by the Board, Respondents shall pay the fines agreed to herein by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of entry of this Order.

16. Upon approval of this Stipulation by the Board, Respondents shall pay the attorney's fees and investigative costs agreed to herein by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of entry of this Order.

17. Subject to the approval of this Stipulation by the Board, the Board and Respondents agree to release one another from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

**Respondents have fully considered the charges and allegations contained in the *First Amended Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and have knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.**

**AGREED:**

**Signed this ___ day of September 2023**

_____
**WALGREENS PHARMACY #6425,**
**Pharmacy License No. PH01594**

**Signed this ___ day of September 2023**

_____
**JUAN PEIDRA FLORES, RPH,**
**Certificate of Registration No. 20887**

**APPROVED AS TO FORM AND CONTENT**
**this ___ day of September 2023**

_____
**WILLIAM J. STILLING, ESQ.**
**Counsel for Respondents**

**Signed this ___ day of September 2023**

_____
**BRETT KANDT, ESQ.**
**General Counsel**
**Nevada State Board of Pharmacy**

## ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondent Walgreens Pharmacy #6425, Pharmacy License No. PH01594, and Respondent Juan Peidra Flores, RPh, Certificate of Registration No. 20887 in Case Nos. 22-359-PH-S and 22-359-RPH-S, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

**IT IS SO ORDERED.**

Entered this ___ day of September 2023.

_____
Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

# 5D

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**JUAN PEIDRA FLORES, RPH,**<br>**Certificate of Registration No. 20887,**<br><br>**Respondent.** | **Case No. 22-359-RPH-S**<br><br>**STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING** |

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a First Amended Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the First Amended Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the First Amended Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the First Amended Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, June 14, 2023, at 9:00 AM PST or soon thereafter at the following location:**

**Hilton Garden Inn Las Vegas Strip South**
**7830 S. Las Vegas Blvd**
**Las Vegas, NV 89123**

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 4th day of May, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

| | |
|---|---|
| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**JUAN PEIDRA FLORES, RPH,**<br>**Certificate of Registration No. 20887,**<br><br>**Respondent.** | **Case No. 22-359-RPH-S**<br><br><br><br><br><br>**ANSWER AND NOTICE OF DEFENSE** |

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the First Amended Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the First Amended Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

**JUAN PEIDRA FLORES, RPH**

# CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 5th day of May 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Juan Peidra Flores, RPH
[redacted]Dalton Lake St.
Las Vegas, NV 89178

Walgreens Pharmacy #06425
900 N. Rancho Dr.
Las Vegas, NV 89106-1005

William Stilling, Esq.
222 South Main Street, Suite 500
Salt Lake City, Utah 84101

SHIRLEY HUNTING

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

| | |
|---|---|
| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br>**v.**<br><br>**WALGREENS PHARMACY #6425, Pharmacy License No. PH01594, and**<br><br>**JUAN PEIDRA FLORES, RPH, Certificate of Registration No. 20887,**<br><br>**Respondents.** | **CASE NOS. 22-359-PH-S**<br>**22-359-RPH-S**<br><br>**STIPULATION AND ORDER** |

Brett Kandt, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondent Juan Peidra Flores, RPh (Flores), Certificate of Registration No. 20887, and Respondent Walgreens Pharmacy #6425, Pharmacy License No. PH01594, jointly by and through counsel**,** William Stilling, Esq. of Stilling & Harrison, **HEREBY STIPULATE AND AGREE THAT**:

1. The Board has jurisdiction over Respondents and these matters.

2. On or about May 4, 2023, Board Staff served Respondents with the First Amended Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondents and Notice of Hearing.

3. Respondents jointly filed an Answer and Notice of Defense to the Accusation.

4. Respondents are aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering this Stipulation.

5. Respondents are aware of the right to a hearing on the matters alleged in the Accusation, their right to reconsideration, their right to appeal, and any and all other rights which may be accorded pursuant to NRS Chapter 233B, Nevada Administrative Procedure Act, NRS

Chapter 622A, Administrative Procedure Before Certain Regulatory Bodies, and NRS Chapter 639, Nevada Pharmacy Act.

6. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondents, or any of them, have failed to comply with the provisions of this Stipulation, Respondents hereby knowingly and voluntarily waive their rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to them by NRS Chapter 233B, Nevada Administrative Procedure Act, NRS Chapter 622A, Administrative Procedure Before Certain Regulatory Bodies, and NRS Chapter 639, Nevada Pharmacy Act.

7. Respondents admit that evidence exists, and that Board's staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in the Accusation, *to wit,* that:

A. Respondent Flores engaged in unprofessional conduct as defined in NAC 639.945(1)(e) and (i) when he twice overrode drug utilization review (DUR) warnings noting that R.C. has an allergy to propylene glycol and failed to contact the prescriber for alternative medication prior to dispensing prescription no. 1949022, resulting in patient harm and subjecting Flores to discipline pursuant to NRS 639.210(4).

B. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondent Walgreens Pharmacy #6425 is responsible for those violations, including all errors and omissions of Flores, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(2).

8. Those violations are plead with particularity in the Accusation and are grounds for action pursuant to NRS 639.210 and NRS 639.255.

9. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Juan Peidra Flores, RPh, Certificate of Registration No. 20887, stipulate to the following penalties:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent Flores shall pay a fine of One-Thousand Dollars ($1,000.00) for the violations; and

B. Pursuant to NRS 622.400, Respondent Flores shall pay Five-Hundred Dollars ($500.00) to partially reimburse the Board for recoverable attorney's fees and investigative costs.

10. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Walgreens Pharmacy #6425, Pharmacy License No. PH01594, stipulate to the following penalties:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent Walgreens Pharmacy #6425 shall pay a fine of Two-Thousand Dollars ($2,000.00) for the violations; and

B. Pursuant to NRS 622.400, Respondent Walgreens Pharmacy #6425 shall pay One-Thousand Dollars ($1,000.00) to partially reimburse the Board for recoverable attorney's fees and investigative costs.

11. Any failure by any Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing the non-compliant Respondent(s) to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by any Respondent, the Board may impose additional discipline upon the non-compliant Respondent(s) consistent with the provisions of NRS Chapter 639.

12. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 6, 2023.

Respondents will appear in person at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondents or counsel are not present at the meeting.

13. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60.

14. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board at a later date. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

15. Upon approval of this Stipulation by the Board, Respondents shall pay the fines agreed to herein by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of entry of this Order.

16. Upon approval of this Stipulation by the Board, Respondents shall pay the attorney's fees and investigative costs agreed to herein by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of entry of this Order.

17. Subject to the approval of this Stipulation by the Board, the Board and Respondents agree to release one another from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

**Respondents have fully considered the charges and allegations contained in the *First Amended Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and have knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.**

**AGREED:**

**Signed this ___ day of September 2023**

_____
**WALGREENS PHARMACY #6425,**
**Pharmacy License No. PH01594**

**Signed this ___ day of September 2023**

_____
**JUAN PEIDRA FLORES, RPH,**
**Certificate of Registration No. 20887**

**APPROVED AS TO FORM AND CONTENT**
**this ___ day of September 2023**

_____
**WILLIAM J. STILLING, ESQ.**
**Counsel for Respondents**

**Signed this ___ day of September 2023**

_____
**BRETT KANDT, ESQ.**
**General Counsel**
**Nevada State Board of Pharmacy**

## ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondent Walgreens Pharmacy #6425, Pharmacy License No. PH01594, and Respondent Juan Peidra Flores, RPh, Certificate of Registration No. 20887 in Case Nos. 22-359-PH-S and 22-359-RPH-S, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

**IT IS SO ORDERED.**

Entered this ___ day of September 2023.

_____
Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

# 5E

FILED
APR 21 2023
NEVADA STATE BOARD OF PHARMACY

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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|---|---|
| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br>**v.**<br><br>**SANDRA LE, RPH,**<br>**Certificate of Registration No. 18241,**<br><br>**KHANH V. PHAM, RPH,**<br>**Certificate of Registration No. 16235, and**<br><br>**CVS PHARMACY #8804,**<br>**Pharmacy License No. PH01093,**<br><br>**Respondents.** | **Case Nos. 19-131-RPH-A-S**<br>**19-131-RPH-B-S**<br>**19-131-PH-S**<br><br>**NOTICE OF INTENDED ACTION AND ACCUSATION** |

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

## JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Sandra Le, RPH ("Respondent Le"), because Respondent Le holds a certificate of registration issued by the Board pursuant to NRS 639.127, authorizing her to engage in the practice of pharmacy within the state of Nevada.

2. The Board has personal jurisdiction over Respondent Khanh V. Pham, RPH ("Respondent Pham"), because Respondent Pham holds a certificate of registration issued by the Board pursuant to NRS 639.127, authorizing him to engage in the practice of pharmacy within the state of Nevada.

3. The Board has personal jurisdiction over Respondent CVS Pharmacy #8804 ("Respondent CVS Pharmacy") because Respondent CVS Pharmacy holds a license issued by the

Board pursuant to NRS 639.230, authorizing Respondent CVS Pharmacy to operate a pharmacy located 1408 West Craig Road in North Las Vegas, Nevada.

4. The Board has jurisdiction over the subject matter of this accusation because, at the time of the violations alleged herein, Respondent Le and Respondent Pham were Nevada registered pharmacists engaged in the practice of pharmacy at a business location operated by Respondent CVS Pharmacy in North Las Vegas, Nevada.

## FACTUAL ALLEGATIONS

5. On or about July 17, 2019, Respondent Le was a registered pharmacist on duty at the CVS Pharmacy #8804 in North Las Vegas, Nevada. While on duty, Respondent Le processed a prescription for patient TC. The prescription was for Endometrin, a medication containing progesterone. Patient TC's physician had written the prescription with instructions to fill a quantity of forty-two suppositories to be inserted vaginally by patient TC three times per day in connection with *in vitro* fertilization ("IVF"). Endometrin is used to increase the level of progesterone in patients undergoing fertility treatments.

6. On or about July 17, 2019, Respondent Le processed another prescription for patient TC in connection with her IVF. Patient TC's physician had written that prescription for a quantity of four 250mg tablets of Zithromax, an antibiotic. The Zithromax prescription was written with instructions for patient TC to take two tablets with dinner on the evening before the IVF procedure and two tablets with breakfast on the morning of the IVF procedure.

7. Pharmaceutical Technician Haydee Martinez (PT Martinez), the holder of license no. PT16676, performed the data entry for the prescription identified in paragraph 5 above. Pharmaceutical Technician Vanessa Cardozo (PT Cardozo), the holder of license no. PT07016, performed the data entry for the prescription identified in paragraph 6 above. Respondent Le performed the verifications for both prescriptions.

8. Regarding the prescription described in paragraph 5 above, PT Martinez mistakenly identified the medication as misoprostol, believing that misoprostol was the generic name for

Endometrin. PT Martinez entered instructions for patient TC to insert one misoprostol tablet vaginally three times per day as directed by her physician. When inserted vaginally, misoprostol is used to terminate a pregnancy, not to assist with fertility treatments.

9. Regarding the prescription described in paragraph 6 above, PT Cardozo correctly identified the medication and the prescribed dose, but she mistakenly entered the prescribed quantity as six 250 mg tablets. PT Cardozo also entered incorrect dosage instructions, advising patient TC to "take two tablets by mouth today, then take 1 tablet daily for 4 days." This conflicted with the physician's instructions to take two tablets with dinner on the evening before the IVF procedure and two tablets with breakfast on the morning of the IVF procedure.

10. Respondent Le verified each of the prescriptions identified in paragraphs 5 and 6 above. Respondent Le did not discover the data entry mistakes by PT Martinez or PT Cardozo. Notably, Respondent Le overrode a DUR system warning pertaining to the data entry error relating to misoprostol. The warning indicated that the stated dose was incorrect and that the medication was contraindicated for persons of child-bearing age. Despite the warning, Respondent verified the prescription as entered.

11. On or about July 20, 2019, Respondent Pham was the registered pharmacist on duty at CVS Pharmacy #8804, when patient TC arrived to pick up her prescription medications prior to her IVF procedure. Respondent Pham neglected to counsel patient TC before she left the pharmacy with an incorrect prescription for misoprostol. Had Respondent Pham properly counseled patient TC, the counseling would have alerted patient TC that she had been given the wrong medication.

12. On or about July 23, 2019, patient TC's physician performed the scheduled IVF procedure, transferring two embryos into patient TC's uterus. Thereafter, in accordance with the instructions that Respondent Le had incorrectly prepared for her, patient TC vaginally inserted the misoprostol that Respondent Le had incorrectly supplied to her. This caused patient TC to suffer from stomach cramps, which in turn prompted patient TC to search for relevant information on the internet.

When she discovered that misoprostol is used to terminate pregnancies, she filed a complaint with the Board.

13. Following receipt of patient TC's complaint, Investigator Dena McClish conducted an investigation. Respondent Le and Respondent CVS Pharmacy fully cooperated with the investigation, providing business records that confirm the allegations stated above. Respondent Pham had left the employ of CVS Pharmacy by the time of the investigation. It is unknown whether patient TC lost her embryos due to the errors and/or omissions described above.

## APPLICABLE LAW

14. The Board may revoke or suspend the registration of any pharmacist who has been guilty of unprofessional conduct or conduct contrary to the public interest. *See* NRS 639.210(4). Likewise, the Board may revoke or suspend the registration of any pharmacist who has violated any provision of Nevada law relating to prescription drugs. *See* NRS 639.210(12). In lieu of revoking or suspending such a pharmacist's registration, the Board may impose fines as a disciplinary measure. *See* NRS 639.255; NAC 639.955.

15. A pharmacist's conduct is deemed unprofessional if the pharmacist fails to strictly follow the instructions of the person writing, making, or ordering a prescription as to its filling or refilling. *See* NAC 639.945(1)(i). Additionally, a pharmacist's conduct is deemed unprofessional if the pharmacist performs his or her duties in an incompetent, unskillful or negligent manner. *See* NAC 639.945(1)(i). Finally, a pharmacist's conduct is deemed unprofessional if the pharmacist fails to confer with the person writing, making or ordering a prescription if there is an error or omission in it which should be questioned. *See* NAC 639.945(1)(e).

16. Unless otherwise provided by law, a pharmacist must verbally provide a patient or a person caring for the patient with information about each prescription drug or device dispensed to the patient. Failure to provide appropriate counseling to the patient constitutes a violation of NRS 639.707(1). Pursuant to NRS 639.210(12), the Board may discipline a pharmacist who violates NRS 639.707(1).

17. Each pharmacy in Nevada must be managed by a registered pharmacist, approved by the Board, who is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. *See* NRS 639.220(1). Pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2), pharmacies, pharmacy mangers, and/or pharmacists are responsible for the acts and omissions of the pharmacy employees under their supervision.

**COUNT ONE**

**Unprofessional Conduct by a Pharmacist (Respondent Le)**

18. On or about July 17, 2019, Respondent Le engaged in unprofessional conduct as described above. Respondent's Le's conduct was unprofessional because: she failed to strictly follow the instructions of patient TC's physician as to the filling of patient TC's prescriptions for Endometrin and Zithromax; she failed to properly verify the data that the pharmacy technician had entered in the pharmacy management system regarding patient TC's prescriptions for Endometrin and Zithromax; and/or she failed to confer with patient TC's physician concerning errors that should have been readily apparent to her after seeing the system warning as described in paragraph 10 above. Any of these mistakes amounts to unprofessional conduct for which the Board may impose discipline pursuant to NRS 639.210(4), NRS 639.255(1), NAC 639.945, and NAC 639.955.

**COUNT TWO**

**Supervisory Liability (Respondent Le)**

19. On or about July 17, 2019, Respondent Le failed to adequately supervise PT Martinez and PT Cardozo, the pharmaceutical technicians who made the data entry mistakes as described above. These technicians were under Respondent Le's supervision at the time. Pursuant to NAC 639.702, the data entry errors and/or omissions may be attributed to Respondent Le. Accordingly, the Board may discipline Respondent Le pursuant to NRS 639.210(4), NRS 639.255(1), NRS 639.945(1), and NAC 639.955.

**COUNT THREE**

**Violation of NRS 639.707(1) (Respondent Pham)**

20. On or about July 20, 2019, Respondent Pham was the pharmacist on duty responsible for counseling patient TC when she arrived at CVS Pharmacy to pick up her prescriptions. By neglecting to counsel patient TC before she left the pharmacy with an incorrect prescription for misoprostol, Respondent Pham violated the provisions NRS 639.707(1). Had Respondent Pham properly counseled patient TC, the counseling would have alerted patient TC that she had been given the wrong medication. Accordingly, the Board may discipline Respondent Pham pursuant to NRS 639.210(12), NRS 639.255(1), and NAC 639.955.

**COUNT FOUR**

**Vicarious Liability (Respondent CVS Pharmacy)**

21. Between July 17 and 20, 2019, Respondent CVS Pharmacy employed Respondent Le and Respondent Pham as staff pharmacists. Pursuant to NRS 639.230(5), NAC 639.702, and NAC 639.945(2), Respondent CVS Pharmacy is liable for their unprofessional conduct and/or statutory violations as described above. Accordingly, the Board may discipline CVS Pharmacy pursuant to NRS 639.210, NRS 639.255, and NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registrations of Respondent Le and Respondent Pham, and the pharmacy license of Respondent CVS Pharmacy.

DATED this 21st day of APRIL 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

## NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**CVS PHARMACY #8804,**<br>**Pharmacy License No. PH01093,**<br><br>**Respondent.** | **CASE NO. 19-131-PH-S**<br><br>**STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING** |

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, June 14, 2023, at 9:00 AM PST or soon thereafter at the following location:**

**Hilton Garden Inn Las Vegas Strip South**
**7830 S. Las Vegas Blvd**
**Las Vegas, NV 89123**

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 21st day of APRIL, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**CVS PHARMACY #8804,**<br>**Pharmacy License No. PH01093,**<br><br>**Respondent.** | **Case No. 19-131-PH-S**<br><br>**ANSWER AND NOTICE OF DEFENSE** |

Respondent above named; in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

**TYPE OR PRINT NAME**

_____

**AUTHORIZED REPRESENTATIVE FOR CVS PHARMACY #8804**

# CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 21st day of April 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Sandra Le, RPH
[redacted] Chorleywood Way
Las Vegas, NV 89131

Khanh V. Pham, RPH
[redacted] Groveton Ct.
Las Vegas, NV 89131

CVS Pharmacy #8804
1408 W. Craig Road
North Las Vegas, NV 89032

Brian J. Convery, Esq.
Pharmacy Regulatory Affairs - CVS Health
200 Campus Drive, Suite 310
Florham Park, NJ 07932

SHIRLEY HUNTING

# 5F

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**SANDRA LE, RPH,**<br>**Certificate of Registration No. 18241,**<br><br>**Respondent.** | **Case No. 19-131-RPH-A-S**<br><br>**STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING** |

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, June 14, 2023, at 9:00 AM PST or soon thereafter at the following location:**

**Hilton Garden Inn Las Vegas Strip South**
**7830 S. Las Vegas Blvd**
**Las Vegas, NV 89123**

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 21st day of APRIL, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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|---|---|
| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**SANDRA LE, RPH,**<br>**Certificate of Registration No. 18241,**<br><br>**Respondent.** | **Case No. 19-131-RPH-A-S**<br><br>**ANSWER AND NOTICE OF DEFENSE** |

Respondent above named; in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

**SANDRA LE, RPH**

# CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 21st day of April 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Sandra Le, RPH
[redacted] Chorleywood Way
Las Vegas, NV 89131

Khanh V. Pham, RPH
[redacted] Groveton Ct.
Las Vegas, NV 89131

CVS Pharmacy #8804
1408 W. Craig Road
North Las Vegas, NV 89032

Brian J. Convery, Esq.
Pharmacy Regulatory Affairs - CVS Health
200 Campus Drive, Suite 310
Florham Park, NJ 07932

SHIRLEY HUNTING

# 5G

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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|---|---|
| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**KHANH V. PHAM, RPH,**<br>**Certificate of Registration No. 16235,**<br><br>**Respondent.** | **Case No. 19-131-RPH-B-S**<br><br>**STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING** |

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

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4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 21st day of APRIL, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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|---|---|
| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**KHANH V. PHAM, RPH,**<br>**Certificate of Registration No. 16235,**<br><br>**Respondent.** | **Case No. 19-131-RPH-B-S**<br><br>**ANSWER AND NOTICE OF DEFENSE** |

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

# CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 21st day of April 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Sandra Le, RPH
[redacted] Chorleywood Way
Las Vegas, NV 89131

Khanh V. Pham, RPH
[redacted] Groveton Ct.
Las Vegas, NV 89131

CVS Pharmacy #8804
1408 W. Craig Road
North Las Vegas, NV 89032

Brian J. Convery, Esq.
Pharmacy Regulatory Affairs - CVS Health
200 Campus Drive, Suite 310
Florham Park, NJ 07932

SHIRLEY HUNTING

# 5H

FILED
JUL - 3 2023
NEVADA STATE BOARD OF PHARMACY

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

**NEVADA STATE BOARD OF PHARMACY,**

**Petitioner,**

**v.**

**CRAIG PIVO, RPH,**
**Certificate of Registration No. 09999,**

**and,**

**GENOA HEALTHCARE LLC,**
**Pharmacy License No. PH03981,**

**Respondents.**

**Case Nos. 20-022-RPH-S**
**20-022-PH-S**

**NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

## JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Craig Pivo ("Respondent Pivo") because Respondent Pivo holds a certificate of registration issued by the Board pursuant to NRS 639.127, authorizing him to engage in the practice of pharmacy within the state of Nevada.

2. The Board has personal jurisdiction over Respondent Genoa Healthcare LLC ("Respondent Genoa") because Respondent Genoa holds a license issued by the Board pursuant to NRS 639.230, authorizing Respondent Genoa to operate a pharmacy at 2500 W. Washinton Avenue in Las Vegas Nevada. The Board had formerly licensed Respondent Genoa to operate a pharmacy at 1901 S. Jones Boulevard in Las Vegas, Nevada.

3. The Board has jurisdiction over the subject matter of this accusation because, at the time of the violations alleged herein, Respondent Pivo was a Nevada registered pharmacist engaged in the

practice of pharmacy at Respondent Genoa's pharmacy at 1901 S. Jones Boulevard in Las Vegas, Nevada.

## FACTUAL ALLEGATIONS

4. At the time of each of the violations alleged herein, Respondent Pivo was a registered pharmacist employed by Respondent Genoa at its pharmacy on 1901 S. Jones Boulevard in Las Vegas, Nevada.

5. On March 4, 2020, while employed by Respondent Genoa, Respondent Pivo was tasked with filling a prescription for adult patient IS. The prescription had been written by the patient's healthcare provider for alprazolam, a medication used to treat anxiety.

6. Upon receiving the prescription for alprazolam, a pharmacy technician incorrectly transferred the information from the hand-written prescription to Respondent Genoa's prescription management system. The pharmacy technician who performed the data entry mistakenly attributed the prescription to patient TS, a 12-year-old boy with a history of receiving prescriptions at Respondent Genoa's pharmacy. Patient TS had a history of receiving prescriptions for various medications related to attention-deficit/hyperactivity disorder (ADHD). Those medications did not include alprazolam.

7. Adult patient IS and minor patient TS share the same last name but are not related. Respondent Pivo performed the verification of patient IS's prescription for alprazolam. Respondent Pivo failed to recognize that the pharmacy technician had incorrectly attributed the prescription to patient TS. Respondent Pivo thereafter caused a supply of 60 alprazolam tablets (1mg) to be delivered to patient TS at his home in Pahrump, Nevada. The supply arrived at patient TS's home on or about March 5, 2020. The supply of alprazolam arrived in a pill bottle with a label instructing patient TS to take the tablets twice daily.

8. Patient TS's caregivers failed to notice that alprazolam was not among the medications that TS was taking for his ADHD. TS's caregivers had recently discussed changing his medications and assumed that Respondent Genoa had delivered the correct medication. They gave TS one tablet that evening, and another tablet the following morning. TS then went to school, where his teachers

noticed that he was staggering and otherwise exhibiting symptoms of a drug overdose. TS returned home and slept for the remainder of the day.

9. On or about March 4, 2020, Respondent Pivo filled patient IS's prescription for alprazolam a second time, this time correctly attributing it to patient IS. Respondent filled the prescription under prescription number 11226, the same prescription number that was previously and incorrectly attributed to patient TS. Respondent Pivo did not contact patient TS or his caregivers to explain the mistake. Respondent voided the previous transaction so that it appeared that prescription number 11226 had only been filled once.

10. On March 26, 2020, Patient IS's health care provider contacted the Board with a complaint about the facts as alleged above. Following receipt of the complaint, Investigator Dena McClish attempted to ascertain why Respondent Genoa's drug utilization review (DUR) system had not flagged the mistakes related to prescription number 11226, and/or why the company's representatives did not disclose or self-report the mistakes after it became apparent that Respondent Pivo had twice filled prescription number 11226.

11. During her investigation, Investigator McClish interviewed Respondent Pivo, among others. In response to questions about his failure to notify TS's caregivers that he had mistakenly delivered alprazolam to TS at his home in Pahrump, Nevada, Respondent Pivo told Investigator McClish that filled prescriptions are accompanied by a toll-free telephone number that patients may call with questions.

12. When Investigator McClish inquired about Respondent Genoa's DUR system, Respondent Genoa's corporate representatives could not explain why its DUR systems had not flagged the mistakes related to prescription number 11226. A corporate representative provided Investigator McClish with written protocols and procedures that were not followed. Respondent Genoa had no record of whether Respondent Pivo offered counseling to patient TS or his caregivers.

13. In 2008, in connection with his application to renew his Nevada certificate of registration, Respondent Pivo was disciplined by the Board for having failed to disclose that he

voluntarily surrendered pharmacist licenses in California and Utah. In the 2008 case, the Board ordered Respondent to enroll in a substance abuse treatment program, among other things, as a condition of retaining his Nevada registration.

## APPLICABLE LAW

14. The Board may revoke or suspend the registration of any pharmacist who has been guilty of unprofessional conduct or conduct contrary to the public interest. *See* NRS 639.210(4). Likewise, the Board may revoke or suspend the registration of any pharmacist who has violated any provision of Nevada law relating to prescription drugs. *See* NRS 639.210(12). In lieu of revoking or suspending such a pharmacist's registration, the Board may impose fines as a disciplinary measure. *See* NRS 639.255; NAC 639.955.

15. A pharmacist's conduct is deemed unprofessional if the pharmacist fails to strictly follow the instructions of the person writing, making, or ordering a prescription as to its filling or refilling. *See* NAC 639.945(1)(i). Additionally, a pharmacist's conduct is deemed unprofessional if the pharmacist performs his or her duties in an incompetent, unskillful or negligent manner. *See* NAC 639.945(1)(i). Finally, a pharmacist's conduct is deemed unprofessional if the pharmacist fails to confer with the person writing, making, or ordering a prescription if there is an error or omission in it which should be questioned. *See* NAC 639.945(1)(e).

16. Unless otherwise provided by law, a pharmacist must verbally provide a patient or a person caring for the patient with information about each prescription drug or device dispensed to the patient. Failure to provide appropriate counseling to the patient constitutes a violation of NAC 639.707(1). Pursuant to NRS 639.210(12), the Board may discipline a pharmacist who violates NAC 639.707(1)

17. Pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2), pharmacies, pharmacy managers, and/or pharmacists are responsible for the acts and omissions of the pharmacy employees under their supervision.

## COUNT ONE
### Unprofessional Conduct by a Pharmacist

18. In March of 2020, as alleged above, Respondent Pivo engaged in unprofessional conduct because he failed to strictly follow the instructions of patient IS's health care provider as to the filling of patient IS's prescription for alprazolam.

19. In March of 2020, Respondent Pivo performed his duties as a pharmacist in an incompetent, unskillful or negligent manner by causing an adult dose of alprazolam to be delivered to and ingested by minor patient TS, thus causing harm to patient TS.

20. Respondent Pivo performed his duties as a pharmacist in an incompetent, unskillful or negligent manner by delaying patient IS's receipt of his prescription medication.

21. Respondent Pivo engaged in unprofessional conduct when he failed to notify and/or confer with TS's health care provider and/or caregivers upon discovering that alprazolam was incorrectly delivered to TS at his home in Pahrump, Nevada.

22. Any one or all of the errors and/or omissions described above amounts to unprofessional conduct for which the Board may discipline Respondent Pivo pursuant to NRS 639.210(4), NRS 639.255(1), NAC 639.945, and NAC 639.955.

23. Respondent Genoa is also subject to discipline because Respondent Genoa is responsible for Respondent Pivo's unprofessional conduct as described above. NRS 639.230(5), NAC 639.702 and NAC 639.945(2).

## COUNT TWO
### Supervisory Liability

24. On or about March 4, 2020, Respondent Pivo failed to adequately supervise the pharmacy technician who made the data entry mistakes described above. The pharmacy technician was under Respondent Pivo's supervision at the time. Pursuant to NAC 639.702, the pharmacy technician's errors and/or omissions may be attributed to Respondent Pivo. Accordingly, the Board may discipline Respondent Pivo pursuant to NRS 639.210(4), NRS 639.255(1), NRS 639.945(1), and NAC 639.955.

25. Respondent Genoa is also subject to discipline because Respondent Genoa is responsible for the unprofessional conduct of Respondent Pivo and/or the pharmacy technician under his supervision. NRS 639.230(5), NAC 639.702 and NAC 639.945(2).

**COUNT THREE**
**Violation of NAC 639.707(1)**

26. On or about March 5, 2020, Respondent Pivo was the pharmacist on duty responsible for counseling patient TS's caregivers regarding the alprazolam that he had caused to be delivered to TS at his home in Pahrump, Nevada. By neglecting to telephone or otherwise contact TS's caregivers before TS ingested alprazolam, Respondent Pivo violated the provisions NAC 639.707(1). Accordingly, the Board may discipline Respondent Pivo pursuant to NRS 639.210(12), NRS 639.255(1), and NAC 639.955.

27. Respondent Genoa is also subject to discipline because Respondent Genoa is responsible for Respondent Pivo's unlawful conduct as described above. NRS 639.230(5), NAC 639.702 and NAC 639.945(2).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent Pivo and the pharmacy license of Respondent Genoa.

DATED this 3rd day of JULY 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

## NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**GENOA HEALTHCARE LLC,**<br>**Pharmacy License No. PH03981,**<br><br>**Respondent.** | **CASE NO. 20-022-PH-S**<br><br>**STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING** |

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, September 6, 2023, at 9:00 AM PST or soon thereafter at the following location:**

**Hilton Garden Inn Las Vegas Strip South**
**7830 S. Las Vegas Blvd**
**Las Vegas, NV 89123**

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 3rd day of July, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**GENOA HEALTHCARE, LLC,**<br>**Pharmacy License No. PH03981,**<br><br>**Respondent.** | **Case No. 20-022-PH-S**<br><br>**ANSWER AND NOTICE OF DEFENSE** |

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

**TYPE OR PRINT NAME**

_____

**AUTHORIZED REPRESENTATIVE FOR GENOA HEALTHCARE, LLC**

# CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 6th day July of 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Genoa Healthcare, LLC
2500 W Washington Ave #103
Las Vegas, NV 89106

Craig Pivo, RPH
[redacted] Hobbyhorse Ave.
Henderson, NV 89012

Darlene Nases
DARLENE NASES

# 5I

BEFORE THE NEVADA STATE BOARD OF PHARMACY

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**CRAIG PIVO, RPH,**<br>**Certificate of Registration No. 09999,**<br><br>**Respondent.** | **Case No. 20-022-RPH-S**<br><br>**STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING** |

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, September 6, 2023, at 9:00 AM PST or soon thereafter at the following location:**

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**Las Vegas, NV 89123**

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 3rd day of July, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

# BEFORE THE NEVADA STATE BOARD OF PHARMACY

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**CRAIG PIVO, RPH,**<br>**Certificate of Registration No. 09999,**<br><br>**Respondent.** | **Case No. 20-022-RPH-S**<br><br>**ANSWER AND NOTICE OF DEFENSE** |

Respondent above-named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

**CRAIG PIVO, RPH**

# CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 6th day July of 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Genoa Healthcare, LLC
2500 W Washington Ave #103
Las Vegas, NV 89106

Craig Pivo, RPH
[redacted] Hobbyhorse Ave.
Henderson, NV 89012

Darlene Nases

DARLENE NASES

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br>**Petitioner,**<br>**v.**<br>**CRAIG PIVO, RPH,**<br>**Certificate of Registration No. 09999,**<br>**Respondent.** | **Case No. 20-022-RPH-S**<br><br>**STIPULATION AND ORDER** |

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through its Senior General Counsel, Gregory L. Zunino, and Respondent Craig Pivo ("Respondent"), Certificate of Registration No. 09999, hereby stipulate and agree as follows:

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondent acknowledges that he understands the terms of this Stipulation and Proposed Order ("Stipulation"), and that he has executed it knowingly and voluntarily.

4. Respondent is aware of his right to a hearing on the matters alleged in the Accusation, his right to reconsideration of a Board determination in a contested case, his right to appeal a Board determination in a contested case, and all other rights afforded him under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

5. Conditioned on the acceptance of this Stipulation by the Board, and excluding the right to challenge any determination that Respondent has failed to comply with the provisions of the paragraphs below, Respondent hereby freely and voluntarily waives his rights to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

6. Respondent admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violation alleged in Count One of the Accusation, *to wit*:

A. On March 4, 2020, while employed as a pharmacist in Las Vegas, Nevada, Respondent filled a prescription for adult patient IS. The prescription had been written by the patient's healthcare provider for alprazolam, a medication used to treat anxiety.

B. Upon receiving the prescription for alprazolam, a pharmacy technician incorrectly transferred the information from the hand-written prescription to the pharmacy's prescription management system. The pharmacy technician who performed the data entry mistakenly attributed the prescription to patient TS, a 12-year-old boy with a history of receiving prescriptions at the pharmacy. Patient TS was then awaiting a prescription for a different drug.

C. Respondent verified the above prescription and failed to recognize that the pharmacy technician had incorrectly attributed the prescription for alprazolam to patient TS. Respondent thereafter caused a supply of 60 alprazolam tablets (1mg) to be delivered to patient TS at his home. Patient TS subsequently ingested two of the tablets and experienced drowsiness and loss of balance while at school.

D. As alleged above, Respondent engaged in unprofessional conduct by failing to strictly follow the instructions of patient IS's physician, by negligently causing an incorrect prescription drug to be delivered to patient TS, and/or by failing to notify patient TS after Respondent was reasonably placed on notice of his mistake concerning the prescription.

E. Based upon the above facts, Respondent is subject to discipline by the Board pursuant to NRS 639.210(4), NRS 639.255(1), NAC 639.945, and NAC 639.955.

7. Respondent has retired from the practice of pharmacy and currently resides in Hawaii. Respondent has notified the Board that he has retired from the practice of pharmacy and has no plans to resume the practice of pharmacy. Respondent's certificate of registration is currently designated as being in a "retired" status. Respondent has been advised that he cannot practice pharmacy in Nevada unless he renews or reinstates his license.

8. In consideration of Respondent's cooperation in this matter, the amount of time that has passed since the offense, and Respondent's retirement, the violations stated in Count Two and Count Three of the Accusation shall be dismissed upon the approval of this Stipulation by the Board.

9. To resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agree to the imposition of the following penalties:

A. Respondent shall pay an administrative fine of One Thousand and 00/100 Dollars ($1000.00) for the violation alleged in Count One of the Accusation. Further, Respondent shall pay the sum of Five Hundred and 00/100 Dollars ($500.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter.

10. Any failure by Respondent to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapter 639.

11. The Board's Senior General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 6, 2023, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent or her attorney fails to appear for the meeting.

12. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

13. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

14. Upon approval of this Stipulation by the Board, Respondent shall pay the fine agreed to herein by *personal, cashiers,* or *certified check* or *money order* made payable to **"State of Nevada, Office of the Treasurer."** Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within thirty (30) days after the effective date of the Board's Order as stated below.

15. Upon approval of this Stipulation by the Board, Respondent shall pay the attorney's fees and costs agreed to herein by *personal, cashiers,* or *certified check* or *money order* made payable to **"Nevada State Board of Pharmacy."** Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of the Board's Order as stated below.

16. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein.

**AGREED:**

**Signed this 11 day of August 2023.**

**CRAIG PIVO**
**Certificate of Registration No. 09999**

**Signed this ____ day of August 2023.**

**NEVADA STATE BOARD OF PHARMACY**

**GREGORY L. ZUNINO**
**Senior General Counsel**

## DECISION AND ORDER

As to Respondent Craig Pivo, Certificate of Registration No. 09999, in Case No. 20-022-RPH-S, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

**IT IS SO ORDERED.**

Entered this ____ day of September 2023.

_____

Helen Park, President
Nevada State Board of Pharmacy

# 5J

FILED
MAY 19 2023
NEVADA STATE BOARD OF PHARMACY

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br>**v.**<br><br>**SMITH'S PHARMACY #390,**<br>**Pharmacy License No. PH01126, and**<br><br>**CHANCE WARR, RPH**<br>**Certificate of Registration No. 21098,**<br><br>**Respondents.** | **Case No. 22-429-PH-N**<br>**22-429-RPH-N**<br><br>**NOTICE OF INTENDED ACTION AND ACCUSATION** |

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

## JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Smith's Pharmacy #390 (Smith's Pharmacy) because Smith's Pharmacy is licensed by the Board to dispense dangerous drugs and controlled substances in Nevada. Smith's Pharmacy holds pharmacy license number PH01126.

2. The Board has personal jurisdiction over Respondent Chance Warr (Warr) because Warr is registered by the Board to engage in the practice of pharmacy in Nevada. Warr holds certificate of registration number 21098.

3. The Board has jurisdiction over the subject matter of this accusation because, as alleged below, Smith's Pharmacy and Warr engaged in conduct that implicates their fitness to dispense dangerous drugs and/or controlled substances in Nevada.

## FACTUAL ALLEGATIONS

4. At all times relevant to this accusation, Smith's Pharmacy operated a pharmacy located at 1855 West Wendover Boulevard in West Wendover, Nevada. Between May 13, 2020, and

September 2, 2021, Smith's Pharmacy employed Alan Minson, certificate of registration number 18352, as its managing pharmacist. After September 2, 2021, Smith's Pharmacy employed Warr as its managing pharmacist. At no time did Smith's Pharmacy notify the Board that Warr had replaced Alan Minson as its managing pharmacist.

5. When Warr assumed his position as managing pharmacist for Smith's Pharmacy, he held a temporary certificate of registration issued by the Board pursuant to NAC 639.200. Warr's temporary certificate of registration expired on March 2, 2022. Warr did not obtain his permanent certificate of registration until April 11, 2022. Smith's Pharmacy continued to employ Warr as its managing pharmacist after March 2, 2022, even though Warr's temporary certificate of registration had expired.

6. Warr had no authority to dispense dangerous drugs and/or controlled substances, or to act as the managing pharmacist of Smith's Pharmacy, after his temporary certificate of registration expired on March 2, 2022, and before he obtained his permanent certificate of registration on April 11, 2022.

7. The expiration date of Warr's temporary certificate of registration appeared on the face of the certificate, thus putting Warr on notice that he was without authority to dispense dangerous drugs and/or controlled substances, or to act as the managing pharmacist of Smith's Pharmacy after March 2, 2022.

8. At no time between March 2, 2022, and April 11, 2022, did Smith's Pharmacy replace Warr with another pharmacist qualified to act as its managing pharmacist. During this time frame, Smith's Pharmacy effectively operated without a managing pharmacist due to the expiration of Warr's temporary certificate of registration.

## APPLICABLE LAW

9. It is unlawful for any person to sell or dispense, or permit to be sold or dispensed, any dangerous drug or controlled substance unless the person holds the appropriate permit or license issued by the Board and complies with the regulations adopted by the Board. NRS 639.100(1).

10. Every person who dispenses dangerous drugs or controlled substances in Nevada must secure and maintain a certificate of registration from the Board based upon demonstrated expertise and training in the practice of pharmacy. NRS 639.120; NRS 639.127; NAC 639.205–.212.

11. "'Dispense' means to deliver a controlled substance or dangerous drug to an ultimate user, patient or subject of research by or pursuant to the lawful order of a practitioner, including the prescribing by a practitioner, administering, packaging, labeling or compounding necessary to prepare the substance for that delivery." NRS 639.0065. "'Deliver' or 'delivery' means the actual, constructive, or attempted transfer of a controlled substance or dangerous drug from one person to another, whether or not there is an agency relationship.

12. Every pharmacy in Nevada must be licensed by the Board to dispense dangerous drugs and/or controlled substances. NRS 639.230; NRS 639.231. Every pharmacy must be managed by a registered pharmacist, approved by the Board, who is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. NRS 639.220. Every pharmacy must promptly notify the Board of a change in the managing pharmacist. NRS 639.220(4).

13. It is unlawful for any person who is not a registered pharmacist to manage a pharmacy or dispense dangerous drugs or controlled substances. NRS 639.284; NRS 639.100(1). A "registered pharmacist" is a natural person registered by the Board to engage in the practice of pharmacy only as authorized by Nevada law. NRS 639.015; NRS 639.120; NRS 639.127; NAC 639.205–.212. A "managing pharmacist" is a registered pharmacist who is responsible for the operation of a pharmacy. NRS 639.0087.

14. The Board may revoke or suspend the license of any pharmacy that has violated any Nevada law or regulation relating to the practice of pharmacy. NRS 639.210(12); NRS 639.230(5). Likewise, the Board may revoke or suspend the certificate of registration of any pharmacist who has violated any Nevada law or regulation relating to the practice of pharmacy. The "practice of pharmacy"

includes the performance or supervision of activities associated with dispensing a dangerous drug or controlled substance. NRS 639.0124.

15. The Board may revoke or suspend the license of any pharmacy, and/or the certificate of registration of any pharmacist, upon finding that the pharmacy and/or pharmacist committed unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

16. A pharmacist commits unprofessional conduct and/or conduct contrary to the public interest when the pharmacist: (1) performs his duties as the holder of a license issued by the Board in an incompetent, unskillful, or negligent manner, *see* NAC 639.945(1)(i); (2) performs or participates in any fraudulent or deceitful practice or transaction, *see* NAC 639.945(1)(h); (3) aids or abets a person not licensed to practice pharmacy in Nevada, *see* NAC 639.945(1)(j); or (4) performs any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration, *see* NAC 639.945(1)(k).

17. Pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2), pharmacies, pharmacy managers; and/or pharmacists are responsible for the acts and omissions of the pharmacy employees under their supervision.

18. In addition to or in lieu of revoking or suspending a license or certificate of registration due to unprofessional conduct and/or conduct that violates Nevada law relating to the practice of pharmacy, the Board may impose an administrative fine upon the offending pharmacy and/or pharmacist. NRS 639.255(1) The fine may not exceed $10,000 for each offense. NRS 639.255(3).

**COUNT ONE**

**Dispensing without a Managing Pharmacist (Smith's Pharmacy)**

19. Between March 2, 2022, and April 11, 2022, Smith's Pharmacy, acting through its employees, agents, and/or representatives, dispensed dangerous drugs and/or controlled substances to consumers in Nevada without having employed a managing pharmacist qualified to supervise the operation of its pharmacy and/or the dispensing activities of its employees, agents, and/or representatives.

20. Smith Pharmacy's conduct as alleged above violated Nevada law relating to the practice of pharmacy, including NRS 639.100(1), NRS 639.220 and NRS 639.284. Further, such conduct was unprofessional and/or contrary to the public interest. Accordingly, Smith's Pharmacy is subject to discipline pursuant to NRS 639.210(4), NRS 639.210(12), and NAC 639.945(1)(k).

## COUNT TWO
### Permitting Others to Dispense without a Registration (Smith's Pharmacy)

21. Between March 2, 2022, and April 11, 2022, Smith's Pharmacy permitted Warr to dispense dangerous drugs and/or controlled substances in Nevada while Warr was not registered by the Board to dispense dangerous drugs and/or controlled substances. Such conduct violated Nevada law relating to the practice of pharmacy, including NRS 639.100(1) and NRS 639.284.

22. Pursuant to NRS 639.210(4) and NAC 639.945(1)(j), the conduct alleged above constitutes unprofessional conduct and/or conduct contrary to the public interest. More specifically, Smith's Pharmacy aided or abetted one or more persons not licensed to practice pharmacy in Nevada.

23. Pursuant to NRS 639.210(4) and/or NRS 639.210(12), Smith's Pharmacy may be disciplined for violating Nevada law and/or for engaging in unprofessional conduct as alleged above.

## COUNT THREE
### Dispensing Without a Registration (Warr)

24. Between March 2, 2022, and April 11, 2022, Warr dispensed dangerous drugs and/or controlled substances in Nevada while employed by Smith's Pharmacy. During this time frame, Warr did not hold a certificate of registration issued by the Board authorizing him to dispense dangerous drugs and/or controlled substances in Nevada.

25. Respondent's conduct as alleged above violated Nevada law relating to the practice of pharmacy, including NRS 639.100(1) and NRS 639.294, and it constitutes unprofessional conduct and/or conduct contrary to the public interest pursuant to NAC 639.945(1)(k). Accordingly, Respondent is subject to discipline pursuant to NRS 639.210(4) and NRS 639.210(12).

## COUNT FOUR
### Performing Duties in a Negligent Manner (Smith's Pharmacy)

26. Between March 2, 2022, and April 11, 2022, Smith's Pharmacy permitted Warr to dispense dangerous drugs and/or controlled substances in Nevada while Warr did not hold a certificate of registration issued by the Board authorizing Warr to dispense dangerous drugs and/or controlled substances.

27. Between March 22, 2022, and April 11, 2022, Smith's Pharmacy employed Warr as its managing pharmacist even though Warr did not hold a certificate of registration issued by the Board authorizing Warr to dispense dangerous drugs and/or controlled substances in Nevada.

28. As the operator of a Nevada-licensed pharmacy, Smith's Pharmacy had a duty to ensure that Warr was properly registered with the Board and/or authorized to serve as the managing pharmacist of Smith's Pharmacy. As of September 2, 2021, Smith's Pharmacy knew or should have known that Warr had recently relocated from Idaho and/or that he did not hold a permanent certificate of registration issued by the Board.

29. By failing to monitor Warr's application for a permanent certificate of registration, and/or by permitting Warr to engage in the practice of pharmacy after his temporary certificate of registration had expired, Smith's Pharmacy performed its duties as the holder of a license and/or registration issued by the Board in an incompetent, unskillful or negligent manner. This constitutes unprofessional conduct for which Smith's Pharmacy may be disciplined pursuant to NRS 639.210(4) and NAC 639.945(1)(i).

## COUNT FIVE
### Engaging in Deceitful Practices (Warr)

30. Between March 2, 2022, and April 11, 2022, Warr dispensed dangerous drugs and/or controlled substances in Nevada while employed by Smith's Pharmacy. During this time frame, Warr did not hold a certificate of registration issued by the Board authorizing him to dispense dangerous drugs and/or controlled substances.

31. By dispensing dangerous drugs and/or controlled substances without a valid certificate of registration, Warr impliedly represented to prescribing practitioners and/or patients that he was authorized by the Board to dispense dangerous drugs and/or controlled substances in Nevada. Warr further represented to patients, to his employer, and/or to his co-workers at Smith's Pharmacy that he was authorized by the Board to serve as the managing pharmacist for Smith's Pharmacy. Respondent knew that these representations were untrue.

32. By making the false representations alleged above, Warr engaged in unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(h).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license of Smith's Pharmacy #390 and the certificate of registration of Chance Warr.

DATED this 19th day of May 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

## NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**SMITH'S PHARMACY #390,**<br>**Pharmacy License No. PH01126,**<br><br>**Respondent.** | **CASE NO. 22-429-PH-N**<br><br>**STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING** |

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, July 12, 2023, at 9:00 AM PST or soon thereafter at the following location:**

**Hyatt Place**
**1790 E Plumb Ln**
**Reno, NV 89502**

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 19th day of May, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**SMITH'S PHARMACY #390,**<br>**Pharmacy License No. PH01126,**<br><br>**Respondent.** | **CASE NO. 22-429-PH-N**<br><br><br><br><br>**ANSWER AND NOTICE OF DEFENSE** |

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

**TYPE OR PRINT NAME**

_____

**AUTHORIZED REPRESENTATIVE FOR SMITH'S PHARMACY #390**

# CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 25th day of May 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Chance Warr, R.Ph.
[redacted]N Cochrane Ln.
Erda, UT 84074

Smith's Pharmacy #390
1855 West Wendover Blvd.
West Wendover, NV 89883

SHIRLEY HUNTING

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br>**v.**<br><br>**SMITH'S PHARMACY #390,**<br>**Pharmacy License No. PH01126,**<br><br>**Respondent.** | **Case No. 22-429-PH-N**<br><br>**STIPULATION AND ORDER** |

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through its Senior General Counsel, Gregory L. Zunino, and Smith's Pharmacy #390 ("Smith's Pharmacy"), by and through its authorized representative, hereby stipulate and agree as follows:

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Smith's Pharmacy and this matter.

2. The Board's staff properly served Smith's Pharmacy with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. The undersigned representative of Smith's Pharmacy hereby warrants and represents that she has all necessary corporate power and authority to execute this Stipulation and Proposed Order ("Stipulation").

4. On behalf of Smith's Pharmacy, the undersigned representative acknowledges that she understands the terms of this Stipulation, and that she has executed it knowingly and voluntarily.

5. On behalf of Smith's Pharmacy, the undersigned representative acknowledges that she is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded the Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, NRS

Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

6. Conditioned on the acceptance of this Stipulation by the Board, and excluding the right to challenge any determination that Smith's Pharmacy has failed to comply with the provisions of the paragraphs below, the undersigned representative hereby freely and voluntarily waives the right to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

7. On behalf of Smith's Pharmacy, the undersigned representative admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violation alleged in Count One of the Accusation, *to wit*:

A. Between May 13, 2020, and September 2, 2021, Smith's Pharmacy employed Alan Minson, certificate of registration number 18352, as its managing pharmacist. After September 2, 2021, Smith's Pharmacy employed Chance Warr (Warr), certificate of registration 21098, as its managing pharmacist.

B. When Warr assumed his position as managing pharmacist for Smith's Pharmacy, he held a temporary certificate of registration issued by the Board pursuant to NAC 639.200. Warr's temporary certificate of registration expired on March 2, 2022. Warr did not obtain his permanent certificate of registration until April 11, 2022.

C. Between March 2, 2022, and April 11, 2022, Smith's Pharmacy operated a pharmacy in Nevada without a managing pharmacist as required by NRS 639.220.

D. Based upon the above facts, Smith's Pharmacy is subject to discipline by the Board pursuant to NRS 639.210, NRS 639.255, NAC 639.945, and NAC 639.955.

8. Based upon an investigation by Smith's Pharmacy, the parties agree that Chance Warr did not work as a pharmacist in Nevada between March 2, 2022, and April 11, 2022. Accordingly, the charges stated in Count Two through Count Five of the Accusation have been dismissed.

9. To resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Smith's Pharmacy agree to the imposition of the following penalties:

A. Smith's Pharmacy shall pay an administrative fine of Two Thousand and 00/100 Dollars ($2000.00) for the violation alleged in Count One of the Accusation.

B. Further, Smith's Pharmacy shall pay the sum of Five Hundred and 00/100 Dollars ($500.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter.

10. Any failure by Smith's Pharmacy to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing the undersigned representative to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation by Smith's Pharmacy, the Board may impose additional discipline upon Smith's Pharmacy not inconsistent with the provisions of NRS Chapter 639.

11. The Board's Senior General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 6, 2023, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if a representative of Smith's Pharmacy fails to appear for the meeting.

12. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

13. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

14. Upon approval of this Stipulation by the Board, Smith's Pharmacy shall pay the fine agreed to herein by *personal, cashiers,* or *certified check* or *money order* made payable to "**State of Nevada, Office of the Treasurer.**" Smith's Pharmacy shall remit payment in full to the Board's Reno

office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within thirty (30) days after the effective date of the Board's Order as stated below.

15. Upon approval of this Stipulation by the Board, Smith's Pharmacy shall pay the attorney's fees and costs agreed to herein by *personal, cashiers,* or *certified check* or *money order* made payable to **"Nevada State Board of Pharmacy." Smith's Pharmacy** shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of the Board's Order as stated below.

16. Subject to the approval of this Stipulation by the Board, the parties agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein.

**AGREED:**

**Signed this 11th day of August 2023.**

**SMITH'S PHARMACY #390**

**By** _____

**Jaime Montuoro, PharmD**
**Division Health Leader**
**Smith's Food and Drug Stores**

**Signed this ____ day of August 2023.**

**NEVADA STATE BOARD OF PHARMACY**

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**GREGORY L. ZUNINO**
**Senior General Counsel**

## DECISION AND ORDER

As to Smith's Pharmacy #390, Pharmacy License No. No. PH01126, in Case No. 22-022-PH-N, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

**IT IS SO ORDERED.**

Entered this ____ day of September 2023.

_____
Helen Park, President
Nevada State Board of Pharmacy

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**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br>**Petitioner,**<br>**v.**<br>**DELTA DRUGS,**<br>**Pharmacy License No. PH04105,**<br>**Respondent.** | **Case No. 20-168-PH-S**<br><br>**NOTICE OF INTENDED ACTION AND ACCUSATION** |

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

## JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Delta Drugs (Respondent), an out-of-state pharmacy, because Respondent is licensed by the Board to dispense dangerous drugs and controlled substances in Nevada. Respondent holds license number PH04105.

2. The Board has jurisdiction over the subject matter of this accusation because at the time of the violations alleged below Respondent was engaged in the "practice of pharmacy" as that term is defined at NRS 639.0124.

## FACTUAL ALLEGATIONS

3. Respondent, a California corporation, operates a pharmacy based in Glendale, California. On or about May 17, 2019, Respondent submitted to the Board its application to conduct business in Nevada as an out-of-state pharmacy. The Board first issued a pharmacy license to Respondent on July 23, 2019.

4. Prior to July 23, 2019, Respondent was licensed to operate a pharmacy in California but not in Nevada. Between October 20, 2018, and July 22, 2019, Respondent sold and delivered dangerous drugs and/or controlled substances to consumers in Nevada. During this time frame, according to

Respondent's own dispensing records, Respondent shipped dangerous drugs and/or controlled substances into Nevada on thirty-one separate occasions.

5. As alleged above, Respondent's activity, and that of its employees, agents, and/or representatives, amounted to "dispensing" as that term is defined at NRS 639.0065.

6. Between October 20, 2018, and July 23, 2019, Respondent employed Michael Groman (Groman) as its pharmacist-in-charge. In its application for a Nevada pharmacy license, Respondent identified Groman as its managing pharmacist. Groman, now deceased, was never registered by the Board to engage in the practice of pharmacy in Nevada.

7. Sometime after July 23, 2019, Respondent employed Jerry Whittemore (Whittemore) as its pharmacist-in-charge. Whittemore cooperated with the Board's investigation of the allegations stated herein. In a written statement dated November 12, 2020, Whittemore confirmed that Respondent had dispensed dangerous drugs and/or controlled substances to patients in Nevada between October 20, 2018, and July 23, 2019.

## APPLICABLE LAW

8. It is unlawful for any person to sell or dispense, or permit to be sold or dispensed, any dangerous drug or controlled substance unless the person holds the appropriate permit or license issued by the Board and complies with the regulations adopted by the Board. NRS 639.100(1).

9. Every person who dispenses dangerous drugs or controlled substances in Nevada must secure and maintain a certificate of registration from the Board based upon demonstrated expertise and training in the practice of pharmacy. NRS 639.120; NRS 639.127; NAC 639.205–.212.

10. "'Dispense' means to deliver a controlled substance or dangerous drug to an ultimate user, patient or subject of research by or pursuant to the lawful order of a practitioner, including the prescribing by a practitioner, administering, packaging, labeling or compounding necessary to prepare the substance for that delivery." NRS 639.0065. "'Deliver' or 'delivery' means the actual, constructive, or attempted transfer of a controlled substance or dangerous drug from one person to another, whether or not there is an agency relationship.

11. Every pharmacy located outside Nevada must be licensed by the Board before shipping any dangerous drug or controlled substance to a consumer in Nevada. NRS 639.23284; NRS 639.230–639.231. Every pharmacy must be managed by a registered pharmacist, approved by the Board, who is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. NRS 639.220.

12. It is unlawful for any person who is not a registered pharmacist to manage a pharmacy or dispense dangerous drugs or controlled substances. NRS 639.284. A "registered pharmacist" is a natural person registered by the Board to engage in the practice of pharmacy only as authorized by Nevada law. NRS 639.015; NRS 639.120; NRS 639.127; NAC 639.205–.212.

13. The Board may revoke or suspend the license of any pharmacy that has violated any Nevada law or regulation relating to the practice of pharmacy. NRS 639.210(12); NRS 639.230(5). The "practice of pharmacy" includes the performance or supervision of activities associated with dispensing a dangerous drug or controlled substance. NRS 639.0124.

14. In addition to or in lieu of revoking or suspending a pharmacy's license for unlawful conduct relating to the practice of pharmacy in Nevada, the Board may impose an administrative fine upon the pharmacy. NRS 639.255(1)(f). The fine may not exceed $10,000 for each offense. NRS 639.255(3).

## COUNT ONE
### Unlawful Practice of Pharmacy

15. Between October 20, 2018, and July 23, 2019, Respondent, acting through its employees, agents, and/or representatives, dispensed dangerous drugs and/or controlled substances to consumers in Nevada. Respondent did so without having obtained a pharmacy license as required by Nevada law.

16. Between October 20, 2018, and July 23, 2019, Respondent allowed its employees, agents, and/or representatives to dispense dangerous drugs and/or controlled substances to consumers

in Nevada even though such persons were not registered by the Board to engage in the practice of pharmacy in Nevada.

17. Respondent's conduct as alleged above violated Nevada law relating to the practice of pharmacy, including NRS 639.100(1), NRS 639.23284, NRS 639.230, and NRS 639.231.

18. Respondent's conduct as alleged above is grounds for discipline insofar as Respondent aided or abetted the unregistered practice of pharmacy in Nevada. *See* NRS 639.210(12).

19. Respondent's conduct as alleged above is grounds for discipline insofar as Respondent negligently subjected its employees, agents, and/or representatives to potential liability for the unregistered practice of pharmacy in Nevada. *See* NRS 639.210(16).

20. Respondent is subject to discipline for any of the acts or violations alleged above. *See* NRS 639.210(12) and (16).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license of Respondent Delta Drugs.

DATED this 3rd day of JULY 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

## NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**DELTA DRUGS,**<br>**Pharmacy License No. PH04105,**<br><br>**Respondent.** | **CASE NO. 20-168-PH-S**<br><br>**STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING** |

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, September 6, 2023, at 9:00 AM PST or soon thereafter at the following location:**

**Hilton Garden Inn Las Vegas Strip South**
**7830 S. Las Vegas Blvd**
**Las Vegas, NV 89123**

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 3rd day of JULY, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**DELTA DRUGS,**<br>**Pharmacy License No. PH04105,**<br><br>**Respondent.** | **CASE NO 20-168-PH-S**<br><br>**ANSWER AND NOTICE OF DEFENSE** |

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

**TYPE OR PRINT NAME**

_____

**AUTHORIZED REPRESENTATIVE FOR DELTA DRUGS**

# CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this _ 6th day July of 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Delta Drugs
437 Fernando Ct.
Glendale, CA 91204

KRISTOPHER MANGOSING

# 5L

FILED
JUN 29 2023
NEVADA STATE BOARD
OF PHARMACY

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br>**v.**<br><br>**RYAN ROSS, PT,**<br>**Certificate of Registration No. PT20827,**<br><br>**Respondent.** | **Case No. 20-027-PT-S**<br><br>**NOTICE OF INTENDED ACTION AND ACCUSATION** |

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and/or NRS 639.241.

## JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Ryan Ross, PT, Certificate of Registration No. PT20827, was a pharmaceutical technician registered with the Board.

## FACTUAL ALLEGATIONS

2. On or about February 4, 2020, Board investigators determined that Respondent was falsely representing himself as a registered pharmacist on social media, specifically Facebook.

## COUNT ONE
### Violation of State Law

3. Any person who fraudulently represents himself or herself to be a registered pharmacist or practitioner is guilty of a misdemeanor. NRS 639.281(1).

4. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

5. By falsely representing himself to be a registered pharmacist, Respondent violated NRS 639.281(1) and is subject to discipline pursuant to NRS 639.210 (12).

**COUNT TWO**

**Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction**

6. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

7. By falsely representing himself to be a registered pharmacist, Respondent was a party to a fraudulent or deceitful practice or transaction, engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 639.210(4).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

Signed this 24th day of June 2023.

J. David Wuest, R.Ph., Executive Secretary,
Nevada State Board of Pharmacy

## NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**RYAN ROSS, PT,**<br>**Certificate Of Registration No. PT20827,**<br><br>**Respondent.** | **Case No. 20-027-PT-S**<br><br>**STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING** |

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, October 11, 2023, at 9:00 AM PST or soon thereafter at the following location:**

**Hilton Garden Inn Las Vegas Strip South**
**7830 S. Las Vegas Blvd**
**Las Vegas, NV 89123**

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 29th day of JUNE, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

# BEFORE THE NEVADA STATE BOARD OF PHARMACY

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**RYAN ROSS, PT,**<br>**Certificate of Registration No. PT20827,**<br><br>**Respondent.** | **CASE NO. 20-027-PT-S**<br><br><br><br><br>**ANSWER AND NOTICE OF DEFENSE** |

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

**RYAN ROSS, PT**

# CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 19th day of July, 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Ryan Ross, PT
[redacted]Spiracle Ave
Henderson, NV 89002

Jeffrey Setness, Esq.
411 E. Bonneville Ave., Ste. 400
Las Vegas, NV 89101

SHIRLEY HUNTING

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br>**v.**<br><br>**RYAN ROSS, PT,**<br>**Certificate of Registration No. PT20827,**<br><br>**Respondent.** | **Case No. 20-027-PT-S**<br><br>**STIPULATION AND ORDER** |

Brett Kandt, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondent Ryan Ross, PT, Certificate of Registration No. PT20827, **HEREBY STIPULATE AND AGREE THAT**:

1. On or about June 29, 2023, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

2. Respondent is fully aware of the right to seek the advice of counsel in this matter prior to entering into this Stipulation.

3. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to him pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

4. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby knowingly and voluntarily waives the rights to a hearing, reconsideration, appeal and any and all other rights related to this action that

may be accorded by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Respondent does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit,* that:

A. By falsely representing himself to be a registered pharmacist, Respondent violated NRS 639.281(1) and is subject to discipline pursuant to NRS 639.210(12); and

B. By falsely representing himself to be a registered pharmacist, Respondent was a party to a fraudulent or deceitful practice or transaction, engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 639.210(4).

6. Those violations are plead with particularity in the Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

7. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent stipulate to the following penalties. The registration of Ryan Ross, PT, Certificate of Registration No. PT20827, Ryan Ross, PT, Certificate of Registration No. PT20827, is suspended pursuant to NRS 639.255(1)(c). The suspension is stayed, and Respondent is placed on probation for a period of one (1) year pursuant to NRS 639.255(1)(b), subject to the following conditions:

A. Pursuant to NRS 639.255(1)(e), Respondent shall accept this Stipulation and Order as a public reprimand;

B. Pursuant to NRS 639.255(1)(f), Respondent shall pay a fine of Five Hundred Dollars ($500.00) for the violations, through monthly payments pursuant to the following schedule:

| Due Date | Amount |
|---|---|
| 10/1/2023 | 50.00 |
| 11/1/2023 | 50.00 |
| 12/1/2023 | 50.00 |
| 1/1/2024 | 50.00 |
| 2/1/2024 | 50.00 |
| 3/1/2024 | 50.00 |
| 4/1/2024 | 50.00 |
| 5/1/2024 | 50.00 |
| 6/1/2024 | 50.00 |
| 7/1/2024 | 50.00 |
| **TOTAL** | **$500.00** |

Respondent shall make the monthly payments of the fine by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Respondent has the right to pre-pay any or all of the payments;

C. Pursuant to NRS 622.400, Respondent shall pay Five Hundred Dollars ($500.00) to partially reimburse the Board for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter, violations, through monthly payments pursuant to the following schedule:

| Due Date | Amount |
|---|---|
| 10/1/2023 | 50.00 |
| 11/1/2023 | 50.00 |
| 12/1/2023 | 50.00 |
| 1/1/2024 | 50.00 |
| 2/1/2024 | 50.00 |
| 3/1/2024 | 50.00 |
| 4/1/2024 | 50.00 |
| 5/1/2024 | 50.00 |
| 6/1/2024 | 50.00 |
| 7/1/2024 | 50.00 |
| **TOTAL** | **$500.00** |

Respondent shall make the monthly payments of the fees and costs by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Respondent has the right to pre-pay any or all of the payments; and

D. Respondent shall comply with all federal and state statutes and regulations regarding the practice of pharmacy, and have no additional charges filed against him while on probation.

Upon successful completion of probation, Respondent's Certificate of Registration No. PT20827 will be fully restored.

8. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may lift the stay, immediately suspend Certificate of Registration No. PT20827, and impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapter 639.

9. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 6, 2023. Respondent or his counsel may appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting.

10. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330

and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

11. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

12. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

**Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.**

**AGREED:**

**Signed this 2 day of August 2023**

**RYAN ROSS, PT**
**Certificate of Registration No. PT20827**

**Signed this ___ day of August 2023**

**BRETT KANDT, ESQ.**
**General Counsel**
**Nevada State Board of Pharmacy**

## DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent Ryan Ross, PT, Certificate of Registration No. PT20827, in Case No. 20-027-PT-S and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

**IT IS SO ORDERED.**

Entered this ___ day of September 2023.

_____

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

# 5M

FILED
MAY 19 2023
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

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| NEVADA STATE BOARD OF PHARMACY,<br><br>Petitioner,<br><br>v.<br><br>PREFERRED HOMECARE,<br>License No. MP00426,<br><br>Respondent. | CASE NO. 22-415-MP-N<br><br>NOTICE OF INTENDED ACTION AND ACCUSATION |

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

## JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Preferred Homecare ("Respondent"), held a Nevada Medical Products Provider License No. MP00426, issued by the Board.

## FACTUAL ALLEGATIONS

2. On or about November 11, 2022, the Board conducted an inspection of Respondent's facility located at 320 S. Rock Blvd. #170, Sparks, Nevada 89502, and discovered that Respondent was operating without an approved administrator for its Medical Products Wholesaler facility.

3. Respondent's previous facility administrator ceased employment in or about August 2022.

4. Respondent failed to notify the Board of the departure of its facility administrator within three (3) business days.

5. Respondent continued its Medical Products Provider operations for more than ren (10) business days without an approved facility administrator.

6. On or about October 25, 2022, Respondent submitted its facility administrator application.

**COUNT ONE**

**Failure to Employ Facility Administrator - Violations of State Law**

7. Respondent failed to comply with NAC 639.694(3) and (4) as well as NAC 639.6957(1)(a) when it neglected to timely notify the Board of the departure of its facility administrator and continued its operations as a Medical Products Provider without timely obtaining approval of a qualified facility administrator; therefore, Respondent is subject to discipline pursuant to NRS 639.210(12).

**COUNT TWO**

**Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties**

8. By violating NAC 639.694(3) and (4) and NAC 639.6957(1)(a), as detailed above, Respondent engaged in unprofessional conduct and conduct contrary to the public interest, as set forth in NAC 639.6941(1)(a), and performed its duties as the holder of a Medical Products Provider license in an incompetent, unskillful, or negligent manner in violation of NAC 639.945(1)(i); therefore, Respondent subject to discipline pursuant NRS 639.210(4).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 14th day of MAY, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

## NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**PREFERRED HOMECARE,**<br>**License No. MP00426,**<br><br>**Respondent.** | **CASE NO. 22-415-MP-N**<br><br>**STATEMENT AND NOTICE OF HEARING** |

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 639.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, July12, 2023, at 9:00 AM PST or soon thereafter at the following location:**

**Hyatt Place**
**1790 E Plumb Lane**
**Reno, NV 89502**

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 19th day of MAY, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

# BEFORE THE NEVADA STATE BOARD OF PHARMACY

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**PREFERRED HOMECARE,**<br>**License No. MP00426,**<br><br>**Respondent.** | **CASE NO. 22-415-MP-N**<br><br>**ANSWER AND NOTICE OF DEFENSE** |

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

**TYPE OR PRINT NAME**

_____

**AUTHORIZED REPRESENTATIVE FOR PREFERRED HOMECARE**

# CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 30th day of May, 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Preferred Homecare
320 S Rock Blvd #170
Reno, NV 89502

Darlene Nases
DARLENE NASES

# 5N

2008
FILED
JUN 06 2023
NEVADA STATE BOARD OF PHARMACY

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br>**v.**<br><br>**CARSON TAHOE REGIONAL HEALTHCARE d.b.a CARSON TAHOE REGIONAL MEDICAL CENTER, Pharmacy License No. IA00531,**<br><br>**and**<br><br>**KELLY SCHOTT, RPH, Certificate of Registration No. 15719,**<br><br>**Respondents.** | **Case No. 23-004-PH-N**<br>**23-004-RPH-N**<br><br>**NOTICE OF INTENDED ACTION AND ACCUSATION** |

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and/or NRS 639.241.

## JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over this matter because, at the time of the events alleged herein, Respondent Carson Tahoe Regional Medical Center ("Carson Tahoe"), held Pharmacy License No. IA00531, issued by the Board, pursuant to NRS 639.230, on June 19, 1995, which authorized Carson Tahoe to operate a pharmacy within the State of Nevada.

2. The Board has personal jurisdiction over this matter because, at the time of the events alleged herein, Respondent, Kelly Schott, RPh. ("Schott"), held Pharmacist Certificate of Registration No. 15719, issued by the Board, pursuant to NRS 639.127, on January 10, 2001, which authorized her to engage in the practice of pharmacy within the State of Nevada.

3. The Board has jurisdiction over the subject matter of this accusation because, at the time of the events alleged herein, Schott was a Nevada registered pharmacist engaged in the practice of pharmacy at Carson Tahoe, an operating Nevada pharmacy.

## PRIOR DISCIPLINE

4. On April 10, 2019, Carson Tahoe entered Stipulation in Case No. 18-041-PH-N to pay a fine of $1,500.00 to the Board to resolve allegations the hospital pharmacy had improperly compounded bupivacaine epidurals resulting in administration by an anesthesiologist of a bupivacaine epidural which erroneously contained a methylparaben preservative, in violation of NAC 639.945(1)(a), (b), (d) and/or (i); NAC 639.6701(1)(a) and (c); NAC 639.6702; NRS 639.230(5); and NAC 639.702.

## FACTUAL ALLEGATIONS

5. Carson Tahoe owns and operates a hospital located at 1600 Medical Parkway in Carson City, Nevada. The hospital is a "medical facility" as that term is defined at NRS 449.0151.

6. To provide its patients with controlled substances and/or dangerous drugs as necessary or appropriate for their treatment at the medical facility, Carson Tahoe holds Pharmacy License No. IA00531 issued by the Board. The license authorizes Carson Tahoe to operate a pharmacy on the premises of its medical facility. The pharmacy is an "institutional pharmacy" as that term is defined at NRS 639.0085.

7. At all times relevant to this accusation, Carson Tahoe employed Schott, Certificate of Registration No. 15719, as the Managing Pharmacist of its institutional pharmacy. As Managing Pharmacist, Schott was responsible for maintaining possession of and controlling access to all dangerous drugs and controlled substances acquired by Carson Tahoe for subsequent use by physicians and other medical practitioners at the medical facility.

8. As relevant to this accusation, Carson Tahoe's institutional pharmacy stored dangerous drugs and controlled substances in Pyxis Medstation RX Systems ("Pyxis machines") for patient administration within the hospital. Carson Tahoe's Pyxis machines were programmed with a fingerprint security system.

9. At all times relevant to this accusation, Carson Tahoe employed Walter Allen Fink, M.D. ("Fink") as the Chief Medical Officer of its medical facility, and it employed Kevin Harlow, M.D. ("Harlow"), as the Chief of Staff of its medical facility. On information and belief, Fink and/or Harlow, acting individually or through subordinates, directed certain of Schott's activities in connection with the management of Carson Tahoe's institutional pharmacy.

10. Carson Tahoe contracted with Clinical Colleagues, Inc. ("Clinical Colleagues") by way of an Anesthesia Services Agreement ("the Agreement") to provide anesthesia services at its medical facility. Pursuant to the Agreement, Carson Tahoe granted hospital privileges to Patsy Langford ("Langford"), a certified registered nurse anesthetist.

11. At no time relevant to this accusation was Langford a "practitioner" as that term is defined at NRS 453.126 and NRS 639.0125.

12. At no time relevant to this accusation was Langford issued a Certificate of Registration to Dispense Controlled Substances in Nevada pursuant to NRS 453.226.

13. Although Langford was not a "practitioner" within the meaning of NRS 453.126 and NRS 639.0125, and did not hold a Certificate of Registration to Dispense Controlled Substances, Carson Tahoe's pharmacy, acting through Schott and/or other pharmacy employees, gave Langford physician/practitioner level independent access to controlled substances stored in certain of Carson Tahoe's Pyxis machines.

14. On information and belief, Fink and/or Harlow, acting individually or through subordinates, directed Schott and/or other pharmacy employees to program Carson Tahoe's Pyxis machines so that Langford could independently access and withdraw dangerous drugs and controlled substances, without a practitioner's order, by applying her fingerprint to a touch screen on the Pyxis machine.

15. On December 19, 2022, Langford, using her fingerprint, accessed the Carson Tahoe Pyxis machine in Operating Room 6 ("OR6"). Langford did so without a practitioner order and selected and administered controlled substances including: 25 mcg fentanyl IT and 0.1 mg morphine sulfate 5 mg/ml to a patient as part of a Cesarean section procedure at Carson Tahoe. On December 19, 2022, Langford also selected and obtained a vial of midazolam 2mg (2mL) from the Pyxis machine in OR6 intended for administration to the same Cesarean section patient; however, the midazolam was not administered to the patient.

16. Carson Tahoe's Care Fusion system reflects Langford regularly used her hospital privileges to access Pyxis machines located throughout Carson Tahoe's hospital to select, order, and administer controlled substances to Carson Tahoe hospital patients.

17. Langford was not authorized to possess or administer controlled substances except under the circumstances authorized by NRS 453.375 and NRS 454.213, all while acting under the supervision of a licensed anesthesiologist.

## APPLICABLE LAW

18. It is unlawful for any person to dispense any drug, poison, medicine or chemical unless the person is a Practitioner and holds the appropriate certificate, license or permit required under NRS 639, 453, or 454, and complies with the regulations adopted by the Board. NRS 639.100; NRS 639.0065; NRS 639.235.

19. A controlled substance may only be delivered to an ultimate user pursuant to the lawful order of a practitioner who holds a DEA registration and is authorized to prescribe controlled substances by the jurisdiction in which he or she is licensed to practice his or her profession. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f)(2); 21 CFR § 1306.03(a)(1); 21 CFR § 1306.04(a); NRS 453.226(1).

20. Nevada does not recognize CRNAs as Practitioners or as professionals with authority to prescribe or enter chart orders for controlled substances. NRS 453.038; NRS 453.126; NRS 453.128; NRS 453.375; NRS 453.377; NRS 639.0125; NRS 639.013; NRS 639.100; NAC 639.442.

21. Supplying or diverting drugs, biologicals, medicines, substances, or devices which are legally sold in pharmacies or by wholesalers, so that unqualified persons can circumvent any law pertaining to the legal sale of such articles constitutes unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(k) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

22. The Board may suspend or revoke a registration if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

23. The Board may suspend or revoke a registration if the holder has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

24. The Board may suspend or revoke a certificate of registration to dispense controlled substances issued pursuant to NRS 453.231 upon a finding that the registrant has committed an act that renders registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

25. Any violation of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy under the supervision of the managing pharmacist is cause for suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5).

26. The owner of a pharmacy, the managing pharmacist of the pharmacy and the registered pharmacist on duty are responsible for the acts and omissions of pharmaceutical

technicians and other personnel who are not pharmacists working in or for the pharmacy, including, but not limited to, any errors committed or unauthorized work performed by such personnel, if the owner, managing pharmacist or registered pharmacist knew or reasonably should have known of the act or omission. NAC 639.702.

27. The owner of any business or facility licensed, certified, or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

28. The Board may impose a fine upon the holder of a certificate, license, or permit issued by the Board for up to $10,000.00 for each violation. NRS 639.255(3).

29. This Accusation constitutes a public record pursuant to NRS 622.330 and any discipline imposed by the Board shall be reported to the National Practitioner Data Bank as required by federal law. Title 42 USC § 1396r–2; 45 CFR Part 60.

## COUNT ONE

**Violations of State Law – Permitting Unlawful Prescribing and/or Charting Order of Controlled Substances**
**(Respondents Carson Tahoe and Schott)**

30. By granting CRNA Langford hospital privileges which included physician/practitioner level independent access to the hospital's Pyxis machines, Carson Tahoe, permitted CRNA Langford to engage in prescribing and/or chart ordering of controlled substances without the appropriate certificate, license, or permit. Therefore, Respondents Carson Tahoe and Schott violated, attempted to violate, assisted or abetted in the violation of, or conspired to violate, or knowingly permitted, allowed, condoned or failed to report violations of NRS 453.226(1); NRS 453.375(1); NRS 453.377; NRS 453.381(1) and (8); NRS 639.100; NRS 639.235(1); and are therefore subject to discipline pursuant to NRS 639.230(5); NAC 639.702; NRS 453.236(1)(e); NRS 453.241(1); NRS 639.210(12); and/or NRS 639.255.

## COUNT TWO

**Violations of Federal Controlled Substances Act – Permitting Unlawful Prescribing and/or Charting Order of Controlled Substances**
**(Respondents Carson Tahoe and Schott)**

31. By granting CRNA Langford hospital privileges which included physician/practitioner level independent access to the hospital's Pyxis machines, Carson Tahoe, permitted CRNA Langford to engage in prescribing and/or chart ordering of controlled substances without the appropriate certificate, license, or permit. Therefore, Respondents Carson Tahoe and Schott violated, attempted to violate, assisted or abetted in the violation of or conspired to violate, or knowingly permitted, allowed, condoned or failed to report violations of 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f)(2); 21 U.S.C. § 841(a); 21 U.S.C. § 846; CFR § 1306.03(a); and/or 21 CFR § 1306.04(a), and are therefore subject to discipline pursuant to NRS 639.230(5); NAC 639.702; NRS 453.236(1)(e); NRS 453.241(1); NRS 639.210(11); and/or NRS 639.255.

**COUNT THREE**

**Violations of State Law - Unprofessional Conduct – Permitting Unlicensed Practice (Respondents Carson Tahoe and Schott)**

32. By granting CRNA Langford hospital privileges which included physician/practitioner level independent access to the hospital's Pyxis machine in OR6, Respondent Carson Tahoe permitted CRNA Langford to engage in prescribing and/or chart ordering of controlled substances without the appropriate certificate, license, or permit. Respondent Carson Tahoe's conduct this conduct constitutes unprofessional conduct as defined in NAC 639.945(1)(i). Therefore, Respondents Carson Tahoe and Schott are subject to discipline pursuant to NRS 639.230(5); NAC 639.702; NAC 639.945(2); NRS 639.210(4) and/or NRS 639.255.

**COUNT FOUR**

**Violations of State Law - Unprofessional Conduct – Permitting Unlicensed Practice (Respondents Carson Tahoe and Schott)**

33. By supplying drugs, biologicals, medicines, substances or devices which are legally sold in pharmacies so that CRNA Langford was able to circumvent Nevada's Pharmacy laws concerning licensed dispensing and sale including: NRS 453.226(1); NRS 453.375(1); NRS 453.377; NRS 453.381(1) and (8); NRS 454.213; NRS 454.215; NRS 639.100; NRS 639.235(1);

Respondents Carson Tahoe and Schott performed their duties as the holder of a Nevada Pharmacy license in an unprofessional manner and engaged in conduct contrary to the public interest as defined by NAC 639.945(1)(g). Therefore, Respondents Carson Tahoe and Schott are subject to discipline pursuant to NRS 639.230(5); NAC 639.702; NAC 639.945(2); NRS 453.236(1)(e), NRS 453.241(1) and NRS 639.210(4).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the license(s) and/or certificate(s) of registration held by these Respondents.

Signed this 6th day of June 2023.

J. David Wuest, R.Ph., Executive Secretary of the Nevada State Board of Pharmacy

## NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**CARSON TAHOE REGIONAL HEALTHCARE d.b.a CARSON TAHOE REGIONAL MEDICAL CENTER, Pharmacy License No. IA00531,**<br><br>**Respondent.** | **Case No. 23-004-PH-N**<br><br>**STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING** |

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

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3. **The Board has scheduled your hearing on this matter for Wednesday, July 12, 2023, at 9:00 AM PST or soon thereafter at the following location:**

**Hyatt Place**
**1790 E Plumb Ln**
**Reno, NV 89502**

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 6th day of June 2023.

J. David Wuest, R.Ph., Executive Secretary of the Nevada State Board of Pharmacy

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**CARSON TAHOE REGIONAL HEALTHCARE d.b.a CARSON TAHOE REGIONAL MEDICAL CENTER, Pharmacy License No. IA00531,**<br><br>**Respondent.** | **Case No. 23-004-PH-N**<br><br>**ANSWER AND NOTICE OF DEFENSE** |

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

**TYPE OR PRINT NAME**

_____

**AUTHORIZED REPRESENTATIVE FOR CARSON TAHOE REGIONAL MEDICAL CENTER**

# CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 6th day of June, 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

John H. Cotton & Associates, Ltd.
7900 West Sahara, Suite 200
Las Vegas, NV 89117

Darlene Nases
DARLENE NASES

# 5O

BEFORE THE NEVADA STATE BOARD OF PHARMACY

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**KELLY SCHOTT, RPH,**<br>**Certificate of Registration No. 15719,**<br><br>**Respondent.** | **CASE NO. 23-004-RPH-N**<br><br>**STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING** |

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, July 12, 2023, at 9:00 AM PST or soon thereafter at the following location:**

**Hyatt Place**
**1790 E Plumb Ln**
**Reno, NV 89502**

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 6th day of June 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**KELLY SCHOTT, RPH,**<br>**Certificate of Registration No. 15719,**<br><br>**Respondent.** | **CASE NO. 23-004-RPH-N**<br><br>**ANSWER AND NOTICE OF DEFENSE** |

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

**KELLY SCHOTT, RPH**

# CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 6th day of June, 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

John H. Cotton & Associates, Ltd.
7900 West Sahara, Suite 200
Las Vegas, NV 89117

Darlene Nases

DARLENE NASES

# 5P

FILED
JUN 29 2023
NEVADA STATE BOARD OF PHARMACY

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br>**Petitioner,**<br>**v.**<br>**EDWARD SOLLESA VICTORIA, MD,**<br>**Certificate of Registration No. CS15199,**<br>**Respondent.** | **CASE NO. 23-113-CS-S**<br><br>**NOTICE OF INTENDED ACTION AND ACCUSATION** |

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

## JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Edward Sollesa Victoria, MD, held a Nevada controlled substance registration, Certificate of Registration No. CS15199, issued by the Board.

## FACTUAL ALLEGATIONS

2. On or about March 3, 2023, the Nevada State Board of Medical Examiners (NSBME) entered an order in Case No. 22-33039-1 and imposed discipline on Respondent's License No. 12452 to practice medicine for engaging in conduct in violation of the standards of practice established by the NSBME, specifically for multiple violations of NRS 630.301(4), NRS 630.3062(1)(a) and NRS 630.3062(1)(b)(2) related to prescribing controlled substances to treat acute pain or chronic pain.

## APPLICABLE LAW

3. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in conformance with the requirements of NRS 639.2391-.23914, *inclusive*, and after review of a patient's utilization report in the Prescription Monitoring Program (PMP) database in conformance with NRS 639.23507. 21 CFR § 1306.04(a); NRS 453.381(1).

4. Performing any duties as the holder of a controlled substance registration or a dispensing practitioner registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

5. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

6. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

7. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

## COUNT ONE

### Violation of Federal Controlled Substances Act

8. By violating NRS Chapter 630 as detailed in the NSBME's order in Case No. 22-33039-1, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 CFR § 1306.04(a), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NRS 639.210(11) and/or NRS 639.23916(3)(b).

## COUNT TWO
### Violations of State Law

9. By violating NRS Chapter 630 as detailed in the NSBME's order in Case No22-33039-1, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.381(1), NRS 639.2391-.23914, *inclusive*, and/or NRS 639.23507, and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b)

## COUNT THREE
### Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

10. By violating NRS Chapter 630 as detailed in the NSBME's order in Case No. 22-33039-1, and by violating 21 CFR § 1306.04(a), NRS 453.381(1), NRS 639.2391-.23914, *inclusive*, and/or NRS 639.23507, Respondent has performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest in violation of NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210(4) and/or NRS 639.23916(3)(b).

## COUNT FOUR
### Commission of Acts that Render Registration Inconsistent with the Public Interest

11. By violating NRS Chapter 630 as detailed in the NSBME's order in Case No. 22-33039-1, and by violating 21 CFR § 1306.04(a), NRS 453.381(1) and/or NRS 639.2391-.23914, *inclusive*, and/or NRS 639.23507, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 24th day of JUNE 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

## NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

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|---|---|
| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**EDWARD SOLLESA VICTORIA, MD,**<br>**Certificate of Registration No. CS15199,**<br><br>**Respondent.** | **CASE NO. 23-113-CS-S**<br><br>**STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING** |

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, September 6, 2023, at 9:00 AM PST or soon thereafter at the following location:**

**Hilton Garden Inn Las Vegas Strip South**
**7830 S. Las Vegas Blvd.**
**Las Vegas, NV 89123**

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 29th day of June, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**EDWARD SOLLESA VICTORIA, MD,**<br>**Certificate of Registration No. CS15199,**<br><br>**Respondent.** | **CASE NO. 23-113-CS-S**<br><br>**ANSWER AND NOTICE OF DEFENSE** |

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

**EDWARD SOLLESA VICTORIA, MD**

# CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 30th day of June 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Edward Victoria, MD
2701 N. Tenaya WY #190
Las Vegas, NV 89128

SHIRLEY HUNTING

# 6

# 6A

FILED
JUN 12 2023
NEVADA STATE BOARD OF PHARMACY

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br>**Petitioner,**<br>**v.**<br>**COBALT MEDICAL SUPPLY, INC.,**<br>**Respondent.** | **Case No. 23-122-O**<br><br>**STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING** |

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

On or about April 24, 2023, the Nevada State Board of Pharmacy ("Board") ordered Respondent Cobalt Medical Supply, Inc. ("Cobalt"), a company based in Wayne, New Jersey, to cease and desist furnishing to persons in Nevada any drugs or medical devices that are restricted by federal law to sale by or on the order of a physician. Additionally, pursuant to NRS 639.2895(3), the Board imposed upon Cobalt a fine of Five Thousand and No/100s Dollars ($5,000.00). By email dated May 11, 2023, Cobalt appealed the fine. Pursuant to NRS 639.070, NRS 639.2895, and NRS 233B.121-.126, *inclusive*, the Board has the authority and jurisdiction to adjudicate Cobalt's appeal. For purposes of said appeal, it is alleged that:

## FACTUAL ALLEGATIONS

1. During an inspection of Pacific Crest Dermatology in Sparks, Nevada, the Board's inspector reviewed shipping documents indicating that on or about March 7, 2023, Cobalt shipped prescription-only drugs and/or medical devices into Nevada. The shipment included cephalexin, clindamycin, and valacyclovir, among other prescription-only products.

2. Cobalt's representatives have stated that they no longer intend to conduct business in Nevada, and that they have stopped shipping prescription-only products into Nevada. Cobalt has appealed the fine referenced above. Cobalt's representatives state that Cobalt is a small company that operates primarily in the Northeastern region of the United States. According to Cobalt's representatives, it is not cost-effective for Cobalt to maintain a license in Nevada.

3. On or about April 24, 2023, the Board served upon Cobalt a letter ordering Cobalt to cease and desist its unlicensed activity in Nevada. By that same letter, the Board imposed upon Cobalt a fine of FIVE THOUSAND and 00/100 DOLLARS ($5,000.00) for the unlicensed furnishing of prescription-only drugs and/or medical devices into and/or within Nevada.

4. By email dated May 11, 2023, Cobalt appealed the Board's order imposing a $5,000 fine as described above.

## APPLICABLE LAW

5. Any manufacturer, wholesaler, or other person engaged in the business of distributing prescription-only medical products within or into Nevada must secure a Nevada license pursuant to NRS 639.233. As used herein, "prescription-only products" means controlled substances, poisons, drugs, devices, or appliances that are restricted by federal law to sale by or on the order of a physician to any person located within Nevada. *See* NRS 639.233.

6. Under Nevada law, the term "drug" is defined to include "[a]rticles and devices intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans." *See* NRS 639.007.

7. The term "wholesaler" is defined to include any "person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale." NRS 639.016.

8. The term manufacturer is defined to include any person who "[d]erives, produces, prepares, compounds, mixes, cultivates, grows or processes any drug or medicine; . . . [r]epackages any drug or medicine for the purposes of resale; or . . . [p]roduces or makes any devices or appliances that are restricted by federal law to sale by or on the order of a physician."

9. The term "medical products provider" means any person sells, leases, or otherwise provides prescription-only medical products to a consumer in Nevada.

10. Nevada licensure is required of out-of-state wholesalers, manufacturers, and medical products providers who sell or ship prescription-only medical products into or within

Nevada. *See* NRS 639.233. Licensure is also required of any such person who "stores" prescription-only medical products in Nevada, or who "solicits or accepts orders" for prescription-only medical products that enter Nevada. *See* NRS 639.233(2).

11. The Board may impose an administrative fine of not more than $5,000.00 against any person who, without a license, engages in any activity that requires licensure by the Board. *See* NRS 639.100(1); NRS 639.2895(3).

## COUNT ONE

## (FURNISHING PRESCRIPTION-ONLY PRODUCTS WITHOUT A LICENSE)

12. By shipping prescription-only medical products into Nevada as alleged above, Cobalt violated the provisions of NRS 639.100(1). Therefore, pursuant to NRS 639.2895(3), Cobalt is liable for a fine of not more than $5,000.00.

## NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 639.2895(2); NRS 233B.127(3). You have the right to a hearing before the Board to answer the allegations and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.127(3); NRS 622A.300(1) and (3). If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

**The Board has scheduled your hearing on this matter for July 12, 2023, at 9:00 a.m. or soon thereafter. The hearing will occur at the at the Hyatt Place Reno-Tahoe Airport, 1790 E. Plumb Lane, Reno, Nevada 89502.**

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. You may request and the Board may at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session. NRS 241.030 and NRS 241.033.

DATED this 12th day of June 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

## CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this June 12, 2023, I personally served a true and correct copy of the foregoing **Statement to the Respondent and Notice of Hearing** by placing a copy in the United States Mail, postage prepaid, addressed to the following:

Cobalt Medical Supply, Inc.

4 Haul Road

Wayne, NJ 07470

Attn: Loida Juan

Darlene Nases

DARLENE NASES

# Nevada State Board of Pharmacy

985 Damonte Ranch Parkway, Suite 206 • Reno, NV 89521
(775) 850-1440 • FAX (775) 850-1444
Web Page: bop.nv.gov


April 24, 2023

**Via Certified Mail and Email**

Cobalt Medical Supply, Inc.
4 Haul Road
Wayne, NJ 07470

Attn: Loida Juan
loidaj@cobaltmed.com

**CEASE-AND-DESIST and CITATION-AND-FINE ORDER: Case No. 23-122-O, Unlicensed Furnishing of Drugs and/or Medical Devices**

Dear Ms. Juan:

The Nevada State Board of Pharmacy (Board) has determined that Cobalt Medical Supply, Inc., based in New Jersey, has engaged in the business of furnishing prescription-only drugs and/or medical devices to persons in Nevada without having secured a license as required by Nevada Revised Statutes (NRS) 639.233. Pursuant to NRS 639.233, any manufacturer or wholesaler of prescription-only drugs and/or medical devices must secure a Nevada license if it receives, stores, or ships such products within or into Nevada.

Under Nevada law, the term "drug" is defined to include "[a]rticles and devices intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans." *See* NRS 639.007. The terms "manufacturer" and "wholesaler" are defined at NRS 639.009 and NRS 639.016, respectively. Nevada licensure is required of out-of-state wholesalers and manufacturers who sell or ship drugs or medical devices "that are restricted by federal law to sale by or on the order of a physician to any person located within this State." See NRS 639.233(1).

During an inspection of Pacific Crest Dermatology in Sparks, Nevada, the Board's inspector reviewed shipping documents indicating that on or about March 7, 2023, Cobalt Medical Supply, Inc. shipped prescription-only drugs and/or medical devices into Nevada. The shipment included cephalexin, clindamycin, and valacyclovir, among other prescription-only products.

Given the above findings, the Board hereby orders Cobalt Medical Supply, Inc. to immediately **CEASE and DESIST** furnishing to persons in Nevada any drugs or medical devices that are restricted by federal law to sale by or on the order of a physician. Further, this notice shall serve as a **CITATION** pursuant to NRS 639.2895(2) for the unlicensed furnishing of drugs and/or medical devices to persons in Nevada. Pursuant to NRS 639.2895(3), the Board has assessed an

**administrative fine** against Cobalt Medical Supply, Inc. in the amount of **Five Thousand and 00/100 Dollars ($5,000.00).**

You must pay this administrative fine within 30 days of receipt of this citation, or otherwise contact Board staff to request an alternative payment plan. Payment must be by *cashier's check*, *certified check* or *money order* made payable to "State of Nevada, Office of the Treasurer," to be received at the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

You have the right to appeal this citation by submitting a written request for a hearing to the Board at the Board's Reno office no later than 30 days after receipt of this notice. *See* NRS 639.2895(2). Please be aware that the foregoing does not preclude the filing of administrative or criminal charges if deemed appropriate based upon evidence not currently available to the Board. If you have any questions, please do not hesitate to contact me at 775-850-1440 or zunino@pharmacy.nv.gov.

Sincerely,

/s/ Gregory L. Zunino
Gregory L. Zunino
Senior General Counsel
(775) 850-1440, ext. 124

## Darlene Nases

**From:** Gregory Zunino
**Sent:** Thursday, May 11, 2023 9:51 AM
**To:** Loida Juan; Monica Segedy
**Cc:** Shirley Hunting; Kristopher Mangosing; Darlene Nases
**Subject:** RE: 23-122-O. Cease & Desist and Citation and Fine Order - Cobalt Medical Supply, Inc.

Dear Ms. Juan and Mr. Mazon,

The Board of Pharmacy will accept the below email as an appeal of the $5,000 fine that was imposed by letter dated April 24, 2023. Based upon my telephone conversation with Ms. Juan, I understand that you have stopped shipping products into the state of Nevada and will not resume any such activity unless you have secured a license. I further understand, based upon cost considerations, that Cobalt has no immediate plans to pursue licensure in Nevada. Instead, it will conduct business in other states. I appreciate your attention to this matter. As I said, the Board will follow up with information regarding the status of your appeal.

Sincerely,

Greg Zunino
Senior General Counsel
Nevada State Board of Pharmacy

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**From:** Loida Juan <loidaj@cobaltmed.com>
**Sent:** Thursday, May 11, 2023 6:59 AM
**To:** Monica Segedy <msegedy@pharmacy.nv.gov>; Gregory Zunino <zunino@pharmacy.nv.gov>
**Subject:** FW: 23-122-O. Cease & Desist and Citation and Fine Order - Cobalt Medical Supply, Inc.

**WARNING** - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Hello State of Nevada,

The customer who is a new customer of Cobalt Medical had ordered multiple pharmaceutical products. We had the customers products on hold for almost 90 days as the doctor was not ready to take delivery. The order had stayed on “hold” in our system with a “drop ship purchase order” from our pharmaceutical wholesale distributor who is registered in the State of Nevada.

We do carry all the products that were sold to “Pacific Derm Crest” located in Sparka Nevada. We are registered with a pharmaceutical wholesale distributor for multiple states so all the products that were sold to Pacific Derm Crest were in our stock. However our system had the products listed as a “DROP SHIP” purchase order which means those pharmaceutical items are to ship from our supplier who is licensed in Nevada and sent directly from our supplier to the end user.

When the order was released, it was quickly put on hold because the customer had stalled her delivery another 2 weeks.

When we put the order back on hold it must have deleted the “DROP SHIP” option per pharmaceutical line item and when the order was released to our warehouse 2 weeks later those items were printed on a pick ticket for FEDEX delivery. It was never our intention to ship from our facility. We have no problem having the customer return all the pharmaceutical items to our facility and we will issue a full refund.

We are hoping that we can avoid paying a maximum fine of $5,000 as we had no intention of sending these items to this customer. This is one of our FIRST sales into Nevada that was from a referral. We do not sell to any customers in this State. We will insure this does not happen again however fining a small business this amount of money is very hurtful to our business. Our sale made by our sales representative will also be losing a large amount of money if this fine is not waived. We appreciate any courtesy considering this was a simple mistake by our system and we have ensured with our system expert this will not happen again.

Please advise.

DANIEL MAZON

Daniel Mazon
Sales Consultant
(973) 305-0730 - Office
(973) 556-1367 - Fax
(201) 916-1809 - Cell
dan@cobaltmed.com

*****DUE TO EXTENDED LEAD TIMES ON REGULAR PRODUCTS, DO NOT LET YOUR INVENTORY RUN LOW, TRY AND STAY AHEAD AT LEAST 1 MONTH ON YOUR COMMON ITEMS*****

---

**From:** Michael Neuhaus <mneuhaus@rammedical.com>
**Sent:** Friday, April 28, 2023 11:03 AM
**To:** Loida Juan <loidaj@cobaltmed.com>
**Cc:** Debby Mazon <debby77548@aol.com>; Daniel Mazon <dan@cobaltmed.com>
**Subject:** Re: 23-122-O. Cease & Desist and Citation and Fine Order - Cobalt Medical Supply, Inc.

Dan

When you have some time, can you put together something in writing of what you wanted to say to appeal this?

> On Apr 28, 2023, at 10:18 AM, Loida Juan <loidaj@cobaltmed.com> wrote:
>
> Good morning, Mike
>
> Have you talked who will do the disputing or contesting with the fine? Has it started yet. Just want to ask because I haven’t done anything on my side yet.
>
> ---
>
> **From:** Loida Juan
> **Sent:** Wednesday, April 26, 2023 9:27 AM

# 7

# 7A

FILED 2052
APR 26 2022
NEVADA STATE BOARD OF PHARMACY

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br>**v.**<br><br>**LAS VEGAS SCRIPTS RX,**<br>**Pharmacy License No. PH03930,**<br><br>**NATHAN EDOUARD, RPH,**<br>**Certificate of Registration No. 19462, and**<br><br>**SHERMAN WASHINGTON, MD,**<br>**Certificate of Registration No. CS24310,**<br><br>**Respondents.** | **CASE NOS. 19-243-PH-S**<br>**19-243-RPH-S**<br>**19-243-CS-S**<br><br>**NOTICE OF INTENDED ACTION AND ACCUSATION** |

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

## JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because at the time of the events alleged herein, Respondent Las Vegas Scripts Rx ("LV Scripts") held a Nevada Pharmacy License No. PH03930, Respondent Nathan Edouard, RPh, ("Edouard") held a Nevada Pharmacist Certificate of Registration No. 19462, and Respondent Sherman Washington, MD, ("Washington") held a Controlled Substance Registration No. CS24310, all issued by the Board.

## FACTUAL ALLEGATIONS

2. Respondent LV Scripts is a pharmacy located at 2920 N. Green Valley Parkway, #814, in Henderson, Nevada.

3. Respondent Edouard was/is the owner of LV Scripts and was/is employed as the managing pharmacist during the alleged and relevant timeframes.

4. Respondent Washington was/is a physician who wrote prescriptions with copied signatures filled by LV Scripts during the relevant timeframes.

5. On or about June 10, 2019, LV Scripts received a prescription written by Dr. M.B. for patient M.W. for "Cold Cough & Chest rub 240 grams". The prescription was designated prescription #4000099 and was compounded with Dimethyl Sulfoxide Liquid and Promethazine-Codeine Syrup, which were not written on the prescription. The ingredients and percentages of each drug were not identified on the prescription label.

6. On or about September 25, 2019, Board inspectors completed their annual inspection at LV Scripts. At the inspection, the following violations were discovered:

a. LV Scripts was shipping prescriptions to California and Arizona where LV Scripts is not licensed.

b. LV Scripts appeared to be filling faxed prescriptions that were not signed by practitioners, but contained copied signatures.

c. LV Scripts did not include the required documentation on prescriptions received by telephone from practitioners. The prescriptions also lacked the name(s) of the person(s) who telephoned the prescription, the date(s) the prescription(s) were received and/or the name(s) of the pharmacist(s) who received the order(s).

d. LV Scripts is providing pre-printed prescription forms for marketing purposes in efforts to promote sales to patients and/or practitioners.

e. Respondent Eduoard was improperly documenting prescriptions received by telephone orders on transferred prescriptions.

## APPLICABLE LAW

7. A pharmacy must be managed by a registered pharmacist who is responsible for compliance by the pharmacy and personnel with all state, and federal laws and regulations regarding the operation of the pharmacy. NRS 639.220(1).

8. Unprofessional conduct includes a licensee failing strictly to follow the instructions of the prescribing practitioner in filling of and/or placing contents on the label of the prescription. NRS 585.485(2)(b)(1); NAC 639.6703(1)(a); NAC 639.945(1)(c), (d).

9. Unprofessional conduct includes a licensee performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

10. Unprofessional conduct includes a licensee performing any act, task, or operation for which licensure, certification, or registration is required without the required licensure, certification, or registration. NAC 639.945(1)(k).

11. Unprofessional conduct includes the use of secret formulas and failure to strictly follow the instructions of the person writing, making, or ordering a prescription, and to specify the content on the label of the prescription. NAC 639.6703(1)(a); NAC 639.945(1)(c), (d).

12. No pharmacist or owner of a pharmacy may offer an unearned rebate. The furnishing to a practitioner by a pharmacist or pharmacy of prescription blanks bearing the name and address of the pharmacy is an unearned rebate. NRS 639.264.

13. A pharmacy owner is responsible for violations committed by the pharmacy's employees. NRS 639.230; NAC 639.702; NAC 639.945.

14. Respondents are subject to discipline for violations pursuant to NRS 453.236, NRS 453.241, NRS 639.210 and/or NRS 639.255.

## COUNT ONE
### Unprofessional Conduct – Failure to Strictly Follow Instructions of Prescribing Practitioner (Respondent Edouard)

15. Respondent Edouard engaged in unprofessional conduct when he failed to strictly follow the directions of the prescribing practitioner when compounding prescription #4000099 for patient M.W., which were compounded with Dimethyl Sulfoxide Liquid, a substance not to be used for medicinal purposes on humans, and Promethazine-Codeine Syrup; the ingredients were not written on the prescription in violation of NRS 585.485(2)(b)(1), NAC 639.6703(1)(a), and NAC 639.945(1)(c)(d), and (i), and Respondent Edouard is therefore subject to discipline pursuant to NRS 639.210(4), (12), and/or NRS 639.255.

## COUNT TWO
### Unprofessional Conduct – Incompetent, Unskillful and Negligent Conduct (Respondents Edouard and Washington)

16. Respondent Edouard engaged in unprofessional conduct and conduct contrary to the public interest, and performed his duties in an incompetent, unskillful or negligent manner when he processed copied signatures on prescriptions for Respondent Washington in violation of NAC 453.440(2), NAC 454.060, and is therefore subject to discipline pursuant to NRS 453.236, NRS 453.241, NRS 639.210, and/or NRS 639.255.

17. Respondent Washington engaged in unprofessional conduct and conduct contrary to the public interest, and performed his duties in an incompetent, unskillful or negligent manner when he allowed his copied signature to be used on prescriptions in violation of NAC 453.440(2), NAC 454.060, and is therefore subject to discipline pursuant to NRS 453.236, NRS 453.241, NRS 639.210, and/or NRS 639.255.

## COUNT THREE
### Failure to Properly Document Prescriptions on Telephoned Orders (Respondent Edouard)

18. Respondent Edouard failed to provide proper documentation of telephoned orders in violation of NAC 639.707(1), (2), and (6)(b), and is therefore subject to discipline pursuant to NRS 639.210(12), (15), and/or NRS 639.255.

## COUNT FOUR
**Unprofessional Conduct – Utilization of Pre-printed Forms as Unearned Rebate**
**(Respondent Edouard)**

19. As a pharmacy owner/pharmacist registered with the Board, Respondent Edouard engaged in unprofessional conduct and conduct contrary to the public interest when he utilized pre-printed forms as unearned rebates in marketing his business in violation of NRS 639.264, NAC 639.945(1)(i), and is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

## COUNT FIVE
**Unprofessional Conduct – Unlicensed Activity**
**(Respondent Edouard)**

20. As a pharmacy owner/pharmacist registered with the Board, Respondent Edouard engaged in unprofessional conduct and conduct contrary to the public interest when he shipped prescriptions to California and Arizona without valid licenses in those jurisdictions in violation of NAC 639.945(1)(k), and is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

## COUNT SIX
**Pharmacy/Pharmacy Owner Responsibility**
**(Respondent LV Scripts)**

21. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, LV Scripts is responsible for those violations, including those of the pharmacy's employees, pursuant to NAC 639.702, NAC 639.945(2) and is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of license(s)/registration(s) of these Respondents.

Signed this 26th day of April 2022.

J. David Wiest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

## NOTICE TO RESPONDENTS

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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|---|---|
| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**LAS VEGAS SCRIPTS RX,**<br>**Pharmacy License No. PH03930,**<br><br>**Respondent.** | **CASE NO. 19-243-PH-S**<br><br>**STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING** |

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, June 1, 2022, at 9:00 AM PST or soon thereafter at the following location:**

**Hilton Garden Inn Las Vegas Strip South**
**7830 S. Las Vegas Blvd**
**Las Vegas, NV 89123**

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 26th day of APRIL, 2022.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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|---|---|
| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**LAS VEGAS SCRIPTS RX,**<br>**Pharmacy License No. PH03930,**<br><br>**Respondent.** | **CASE NO. 19-243-PH-S**<br><br>**ANSWER AND NOTICE OF DEFENSE** |

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2022.

_____

**TYPE OR PRINT NAME**

_____

**AUTHORIZED REPRESENTATIVE FOR LAS VEGAS SCRIPTS RX**

# CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28th day of April 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Sherman Washington, MD
[redacted] S. Rainbow Blvd. Suite 100
Las Vegas, NV 89118

Sherman Washington, MD
Transforming Arts
[redacted] N. Green Valley Pkwy., Suite 114
Henderson, NV 89014

Sherman Washington, MD
[redacted] E Lake Mead Blvd Ste M
North Las Vegas, NV 89030

Nathan Edouard, RPH
[redacted] N. Green Valley Pkw Bldg. 8 Ste# 814
Henderson, NV 89014

Las Vegas Scripts Rx
2920 N. Green Valley Pkwy #814
Henderson, NV 89014

SHIRLEY HUNTING

FILED
SEP 08 2022
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

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| **NEVADA STATE BOARD OF PHARMACY,**<br>**Petitioner,**<br>**v.**<br>**LAS VEGAS SCRIPTS RX,**<br>**Pharmacy License No. PH03930,**<br>**NATHAN EDOUARD, RPH,**<br>**Certificate of Registration No. 19462, and**<br>**SHERMAN WASHINGTON, MD,**<br>**Certificate of Registration No. CS24310,**<br>**Respondents.** | **CASE NOS. 19-243-PH-S**<br>**19-243-RPH-S**<br>**19-243-CS-S**<br><br>**FINDINGS OF FACTS, CONCLUSIONS OF LAW, AND ORDER FOR RESPONDENTS LAS VEGAS SCRIPTS RX, AND NATHAN EDOUARD, RPH ONLY** |

This matter came before the Nevada State Board of Pharmacy ("Board") at its regularly scheduled meeting on Thursday, September 8, 2022, in Las Vegas, Nevada. Courtney K. Lee, Esq., appeared on behalf of Petitioner Board. Respondent Las Vegas Scripts, Rx ("LV Scripts"), Pharmacy License No. PH03930, and Nathan Edouard, RPH ("Edouard"), appeared jointly through counsel Chandon Alexander, Esq. of Spartacus Law Firm. Respondent Sherman Washington, MD ("Washington"), appeared through counsel Michael Mee, Esq., and agreed to a separately executed Stipulation and Order. Upon hearing the case, and based upon the evidence presented, the Board determined the following Findings of Facts, Conclusions of Law, and Order ("Order").

## FINDINGS OF FACTS

The allegations against Respondents, as stated in the Notice of Intended Action and Accusation ("Accusation") on file herein, and upon which the Board determined findings of facts, incorporated along with the parties' stipulated facts, are as follows:

1. The Board has jurisdiction over Respondents because at the time of the events alleged herein, Respondent LV Scripts held Pharmacy License No. PH03930 with the Board, and

Respondent Edouard held a pharmacist registration, Certificate of Registration No. 19462 with the Board.

2. Respondent LV Scripts Rx is a pharmacy located 2920 N. Green Valley Parkway, #814, in Henderson, Nevada.

3. Respondent Edouard was/is the owner of LV Scripts and was/is employed as the managing pharmacist during the alleged and relevant timeframes.

4. Respondent Washington was/is a physician who wrote prescriptions with copied signatures filled by LV Scripts during the relevant timeframes.

5. On or about June 10, 2019, LV Scripts received a prescription written by Dr. M.B. for patient M.W. for "Cold Cough & Chest rub 240 grams". The prescription was designated prescription #4000099 and was compounded with Dimethyl Sulfoxide Liquid and Promethazine-Codeine Syrup, which were not written on the prescription.

6. On or about September 25, 2019, Board inspectors completed their annual inspection at LV Scripts. At the inspection, the following violations were discovered:

a. LV Scripts appeared to be filling faxed, hand-delivered, or picked up prescriptions that were not signed by practitioners, but contained copied signatures.

b. LV Scripts is providing pre-printed prescription forms.

c. Respondent Edouard failed to provide proper documentation of telephoned orders.

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## CONCLUSIONS OF LAW

Based upon the foregoing findings of facts, the Board concludes as a matter of law:

7. Respondent Edouard engaged in unprofessional conduct when he failed to strictly follow the directions of the prescribing practitioner when compounding prescription #4000099 for patient M.W., which were compounded with Dimethyl Sulfoxide Liquid, a substance not to be used for medicinal purposes on humans, and Promethazine-Codeine Syrup; the ingredients were not written on the prescription in violation of NRS 585.485(2)(b)(1), NAC 639.6703(1)(a), and NAC 639.945(1)(c)(d), and (i), and Respondent Edouard is therefore subject to discipline pursuant to NRS 639.210(4), (12), and/or NRS 639.255.

8. Respondent Edouard engaged in unprofessional conduct and conduct contrary to the public interest, and performed his duties in an incompetent, unskillful or negligent manner when he processed copied signatures on prescriptions for Respondent Washington in violation of NAC 453.440(2), NAC 454.060, and is therefore subject to discipline pursuant to NRS 453.236, NRS 453.241, NRS 639.210, and/or NRS 639.255.

9. Respondent Edouard failed to provide proper documentation of telephoned orders in violation of NAC 639.712, and is therefore subject to discipline pursuant to NRS 639.210(12), (15), and/or NRS 639.255.

10. As a pharmacy owner/pharmacist registered with the Board, Respondent Edouard engaged in unprofessional conduct and conduct contrary to the public interest when he utilized pre-printed forms as unearned rebates in marketing his business in violation of NRS 639.264, NAC 639.945(1)(i), and is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

11. As the pharmacy at which the violations of law alleged herein occurred, Respondent LV Scripts is responsible for those violations, including those of the pharmacy's employees, pursuant to NAC 639.702, NAC 639.945(2) and is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

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## ORDER

THEREFORE, BASED UPON THE FINDINGS OF FACTS, AND CONCLUSIONS OF LAW, THE BOARD HEREBY ORDERS AS FOLLOWS:

1. Respondent LV Scripts' Pharmacy License No. PH03930 is revoked; however, the revocation is immediately stayed. Respondent LV Scripts shall be placed on probation for two (2) years from the date of entry of the Order. During the 2-year probationary period, Respondent LV Scripts shall not violate any federal or state law pertaining to the dispensing of controlled substances and/or dangerous drugs. If Respondent LV Scripts successfully completes the conditions of the probationary period, then after 2 years, Respondent's Pharmacy License No. PH03930 shall be fully restored.

2. Respondent LV Scripts shall pay fines of Ten Thousand Dollars ($10,000) for the violations by *personal check, business check*, *cashier's check* or *certified check* or *money order* made payable to **"State of Nevada, Office of the Treasurer,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, on the following payment schedule:

| Due Date | Amount |
|---|---|
| 10/1/2022 | $1,000 |
| 11/1/2022 | $1,000 |
| 12/1/2022 | $1,000 |
| 1/1/2023 | $1,000 |
| 2/1/2023 | $1,000 |
| 3/1/2023 | $1,000 |
| 4/1/2023 | $1,000 |
| 5/1/2023 | $1,000 |
| 6/1/2023 | $1,000 |

| | |
|---|---|
| 7/1/2023 | $1,000 |
| ***TOTAL** | **$10,000** |

*Respondent LV Scripts may pre-pay a portion or all of the fines without penalty.

3. Respondent LV Scripts shall pay attorney's fees and investigative costs of Nine Hundred-Forty Dollars and Fifty Cents ($940.50) by *personal check, business check, cashier's check* or *certified check* or *money order* made payable to "**Nevada State Board of Pharmacy,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days upon entry of Order.

4. Respondent LV Scripts shall be subject to quarterly inspections by Board's staff for a period of two (2) years from entry of Order at Respondent LV Scripts' cost, not to exceed Five Hundred Dollars ($500) for each quarterly inspection.

5. Respondent LV Scripts shall ensure that all pharmacist staff who will engage in compounding have completed compounding training approved by Board staff pursuant to NAC 639.67013 within six (6) months of entry of Order.

6. Respondent Edouard's pharmacist registration, Certification of Registration No. 19462 is revoked; however, the revocation is immediately stayed. Respondent Edouard shall be placed on probation for five (5) years from the date of entry of the Order. During the 5-year probationary period, Respondent Edouard shall not violate any federal or state law pertaining to the dispensing of controlled substances and/or dangerous drugs. If Respondent Edouard successfully completes the conditions of the probationary period, then after 5 years, Respondent's Certificate of Registration No. 19462 shall be fully restored.

7. Respondent Edouard shall not be a managing pharmacist for any pharmacy for a period of two (2) years from entry of Order.

8. Respondent Edouard shall pay fines of Five Thousand Dollars ($5,000) for the violations by *personal check, business check*, *cashier's check* or *certified check* or *money order* made payable to **"State of Nevada, Office of the Treasurer,"** to be received by the Board's

Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, on the following payment schedule:

| Due Date | Amount |
|---|---|
| 10/1/2022 | $1,000 |
| 11/1/2022 | $1,000 |
| 12/1/2022 | $1,000 |
| 1/1/2023 | $1,000 |
| 2/1/2023 | $1,000 |
| ***TOTAL** | **$5,000** |

*Respondent Edouard may pre-pay a portion or all of the fines without penalty.

9. Respondent Edouard shall pay attorney's fees and investigative costs of Nine Hundred Dollars ($900) by *personal check, business check, cashier's check* or *certified check* or *money order* made payable to "**Nevada State Board of Pharmacy,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days upon entry of Order.

10. Respondent Edouard must complete two (2) additional hours of continuing education by attending two (2) discipline days of Board meetings within one (1) year upon entry of Order.

11. This Order shall be a public record pursuant to NRS 622.330, and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r-2 and 45 CFR Part 60.

12. Any failure by any Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next scheduled Board meeting for hearing. If the show cause hearing results in a finding of a violation of this Order by any

Respondent, then the Board may impose additional discipline upon any Respondent consistent with NRS Chapter 639.

13. This Order is effective immediately.

**IT IS SO ORDERED.**

Entered this 8th day of September, 2022.

Helen Park, President
Nevada State Board of Pharmacy

# CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 23nd day of September 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Las Vegas Scripts Rx
2920 N. Green Valley Pkwy Ste 814
Henderson, NV 89014

9171 9690 0935 0270 0152 51

Nathan Edouard
[redacted]N. Green Valley Pkwy Ste 814
Henderson, NV 89014

9171 9690 0935 0270 0152 44

Chandon Alexander
2777 Paradise Rd, Suite 3006
Las Vegas, NV 89109

9171 9690 0935 0270 0152 37

KRISTOPHER MANGOSING

# 7B

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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|---|---|
| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**NATHAN EDOUARD, RPH,**<br>**Certificate of Registration No. 19462,**<br><br>**Respondent.** | **CASE NO. 19-243-RPH-S**<br><br>**STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING** |

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, June 1, 2022, at 9:00 AM PST or soon thereafter at the following location:**

**Hilton Garden Inn Las Vegas Strip South**
**7830 S. Las Vegas Blvd**
**Las Vegas, NV 89123**

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 26th day of April, 2022.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

| | |
|---|---|
| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**NATHAN EDOUARD, RPH,**<br>**Certificate of Registration No. 19462,**<br><br>**Respondent.** | **CASE NO. 19-243-RPH-S**<br><br>**ANSWER AND NOTICE OF DEFENSE** |

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2022.

_____
NATHAN EDOUARD, RPH,

# CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28th day of April 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Sherman Washington, MD
[redacted] S. Rainbow Blvd. Suite 100
Las Vegas, NV 89118

Sherman Washington, MD
Transforming Arts
[redacted] N. Green Valley Pkwy., Suite 114
Henderson, NV 89014

Sherman Washington, MD
[redacted] E Lake Mead Blvd Ste M
North Las Vegas, NV 89030

Nathan Edouard, RPH
[redacted] N. Green Valley Pkw Bldg. 8 Ste# 814
Henderson, NV 89014

Las Vegas Scripts Rx
2920 N. Green Valley Pkwy #814
Henderson, NV 89014

SHIRLEY HUNTING

FILED
SEP 08 2022
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

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| **NEVADA STATE BOARD OF PHARMACY,**<br>**Petitioner,**<br>**v.**<br>**LAS VEGAS SCRIPTS RX,**<br>**Pharmacy License No. PH03930,**<br>**NATHAN EDOUARD, RPH,**<br>**Certificate of Registration No. 19462, and**<br>**SHERMAN WASHINGTON, MD,**<br>**Certificate of Registration No. CS24310,**<br>**Respondents.** | **CASE NOS. 19-243-PH-S**<br>**19-243-RPH-S**<br>**19-243-CS-S**<br><br>**FINDINGS OF FACTS, CONCLUSIONS OF LAW, AND ORDER FOR RESPONDENTS LAS VEGAS SCRIPTS RX, AND NATHAN EDOUARD, RPH ONLY** |

This matter came before the Nevada State Board of Pharmacy ("Board") at its regularly scheduled meeting on Thursday, September 8, 2022, in Las Vegas, Nevada. Courtney K. Lee, Esq., appeared on behalf of Petitioner Board. Respondent Las Vegas Scripts, Rx ("LV Scripts"), Pharmacy License No. PH03930, and Nathan Edouard, RPH ("Edouard"), appeared jointly through counsel Chandon Alexander, Esq. of Spartacus Law Firm. Respondent Sherman Washington, MD ("Washington"), appeared through counsel Michael Mee, Esq., and agreed to a separately executed Stipulation and Order. Upon hearing the case, and based upon the evidence presented, the Board determined the following Findings of Facts, Conclusions of Law, and Order ("Order").

## FINDINGS OF FACTS

The allegations against Respondents, as stated in the Notice of Intended Action and Accusation ("Accusation") on file herein, and upon which the Board determined findings of facts, incorporated along with the parties' stipulated facts, are as follows:

1. The Board has jurisdiction over Respondents because at the time of the events alleged herein, Respondent LV Scripts held Pharmacy License No. PH03930 with the Board, and

Respondent Edouard held a pharmacist registration, Certificate of Registration No. 19462 with the Board.

2. Respondent LV Scripts Rx is a pharmacy located 2920 N. Green Valley Parkway, #814, in Henderson, Nevada.

3. Respondent Edouard was/is the owner of LV Scripts and was/is employed as the managing pharmacist during the alleged and relevant timeframes.

4. Respondent Washington was/is a physician who wrote prescriptions with copied signatures filled by LV Scripts during the relevant timeframes.

5. On or about June 10, 2019, LV Scripts received a prescription written by Dr. M.B. for patient M.W. for "Cold Cough & Chest rub 240 grams". The prescription was designated prescription #4000099 and was compounded with Dimethyl Sulfoxide Liquid and Promethazine-Codeine Syrup, which were not written on the prescription.

6. On or about September 25, 2019, Board inspectors completed their annual inspection at LV Scripts. At the inspection, the following violations were discovered:

a. LV Scripts appeared to be filling faxed, hand-delivered, or picked up prescriptions that were not signed by practitioners, but contained copied signatures.

b. LV Scripts is providing pre-printed prescription forms.

c. Respondent Edouard failed to provide proper documentation of telephoned orders.

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## CONCLUSIONS OF LAW

Based upon the foregoing findings of facts, the Board concludes as a matter of law:

7. Respondent Edouard engaged in unprofessional conduct when he failed to strictly follow the directions of the prescribing practitioner when compounding prescription #4000099 for patient M.W., which were compounded with Dimethyl Sulfoxide Liquid, a substance not to be used for medicinal purposes on humans, and Promethazine-Codeine Syrup; the ingredients were not written on the prescription in violation of NRS 585.485(2)(b)(1), NAC 639.6703(1)(a), and NAC 639.945(1)(c)(d), and (i), and Respondent Edouard is therefore subject to discipline pursuant to NRS 639.210(4), (12), and/or NRS 639.255.

8. Respondent Edouard engaged in unprofessional conduct and conduct contrary to the public interest, and performed his duties in an incompetent, unskillful or negligent manner when he processed copied signatures on prescriptions for Respondent Washington in violation of NAC 453.440(2), NAC 454.060, and is therefore subject to discipline pursuant to NRS 453.236, NRS 453.241, NRS 639.210, and/or NRS 639.255.

9. Respondent Edouard failed to provide proper documentation of telephoned orders in violation of NAC 639.712, and is therefore subject to discipline pursuant to NRS 639.210(12), (15), and/or NRS 639.255.

10. As a pharmacy owner/pharmacist registered with the Board, Respondent Edouard engaged in unprofessional conduct and conduct contrary to the public interest when he utilized pre-printed forms as unearned rebates in marketing his business in violation of NRS 639.264, NAC 639.945(1)(i), and is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

11. As the pharmacy at which the violations of law alleged herein occurred, Respondent LV Scripts is responsible for those violations, including those of the pharmacy's employees, pursuant to NAC 639.702, NAC 639.945(2) and is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255.

/ / /

## ORDER

THEREFORE, BASED UPON THE FINDINGS OF FACTS, AND CONCLUSIONS OF LAW, THE BOARD HEREBY ORDERS AS FOLLOWS:

1. Respondent LV Scripts' Pharmacy License No. PH03930 is revoked; however, the revocation is immediately stayed. Respondent LV Scripts shall be placed on probation for two (2) years from the date of entry of the Order. During the 2-year probationary period, Respondent LV Scripts shall not violate any federal or state law pertaining to the dispensing of controlled substances and/or dangerous drugs. If Respondent LV Scripts successfully completes the conditions of the probationary period, then after 2 years, Respondent's Pharmacy License No. PH03930 shall be fully restored.

2. Respondent LV Scripts shall pay fines of Ten Thousand Dollars ($10,000) for the violations by *personal check, business check*, *cashier's check* or *certified check* or *money order* made payable to **"State of Nevada, Office of the Treasurer,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, on the following payment schedule:

| Due Date | Amount |
|---|---|
| 10/1/2022 | $1,000 |
| 11/1/2022 | $1,000 |
| 12/1/2022 | $1,000 |
| 1/1/2023 | $1,000 |
| 2/1/2023 | $1,000 |
| 3/1/2023 | $1,000 |
| 4/1/2023 | $1,000 |
| 5/1/2023 | $1,000 |
| 6/1/2023 | $1,000 |

| | |
|---|---|
| 7/1/2023 | $1,000 |
| ***TOTAL** | **$10,000** |

*Respondent LV Scripts may pre-pay a portion or all of the fines without penalty.

3. Respondent LV Scripts shall pay attorney's fees and investigative costs of Nine Hundred-Forty Dollars and Fifty Cents ($940.50) by *personal check, business check, cashier's check* or *certified check* or *money order* made payable to "**Nevada State Board of Pharmacy,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days upon entry of Order.

4. Respondent LV Scripts shall be subject to quarterly inspections by Board's staff for a period of two (2) years from entry of Order at Respondent LV Scripts' cost, not to exceed Five Hundred Dollars ($500) for each quarterly inspection.

5. Respondent LV Scripts shall ensure that all pharmacist staff who will engage in compounding have completed compounding training approved by Board staff pursuant to NAC 639.67013 within six (6) months of entry of Order.

6. Respondent Edouard's pharmacist registration, Certification of Registration No. 19462 is revoked; however, the revocation is immediately stayed. Respondent Edouard shall be placed on probation for five (5) years from the date of entry of the Order. During the 5-year probationary period, Respondent Edouard shall not violate any federal or state law pertaining to the dispensing of controlled substances and/or dangerous drugs. If Respondent Edouard successfully completes the conditions of the probationary period, then after 5 years, Respondent's Certificate of Registration No. 19462 shall be fully restored.

7. Respondent Edouard shall not be a managing pharmacist for any pharmacy for a period of two (2) years from entry of Order.

8. Respondent Edouard shall pay fines of Five Thousand Dollars ($5,000) for the violations by *personal check, business check*, *cashier's check* or *certified check* or *money order* made payable to **"State of Nevada, Office of the Treasurer,"** to be received by the Board's

Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, on the following payment schedule:

| Due Date | Amount |
|---|---|
| 10/1/2022 | $1,000 |
| 11/1/2022 | $1,000 |
| 12/1/2022 | $1,000 |
| 1/1/2023 | $1,000 |
| 2/1/2023 | $1,000 |
| ***TOTAL** | **$5,000** |

*Respondent Edouard may pre-pay a portion or all of the fines without penalty.

9. Respondent Edouard shall pay attorney's fees and investigative costs of Nine Hundred Dollars ($900) by *personal check, business check, cashier's check* or *certified check* or *money order* made payable to "**Nevada State Board of Pharmacy,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days upon entry of Order.

10. Respondent Edouard must complete two (2) additional hours of continuing education by attending two (2) discipline days of Board meetings within one (1) year upon entry of Order.

11. This Order shall be a public record pursuant to NRS 622.330, and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r-2 and 45 CFR Part 60.

12. Any failure by any Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next scheduled Board meeting for hearing. If the show cause hearing results in a finding of a violation of this Order by any

Respondent, then the Board may impose additional discipline upon any Respondent consistent with NRS Chapter 639.

13. This Order is effective immediately.

**IT IS SO ORDERED.**

Entered this 8th day of September, 2022.

Helen Park, President
Nevada State Board of Pharmacy

# CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 23nd day of September 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Las Vegas Scripts Rx
2920 N. Green Valley Pkwy Ste 814
Henderson, NV 89014

9171 9690 0935 0270 0152 51

Nathan Edouard
2920 N. Green Valley Pkwy Ste 814
Henderson, NV 89014

9171 9690 0935 0270 0152 44

Chandon Alexander
2777 Paradise Rd, Suite 3006
Las Vegas, NV 89109

9171 9690 0935 0270 0152 37

KRISTOPHER MANGOSING

# 8

# 8A

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/02/2022)

| Facility Location | Application Type (check all applicable) | Pharmacy Type (check all applicable) | Services the Pharmacy will Provide (check all applicable) |
|---|---|---|---|
| ☐ Nevada<br>☒ Out-of-State | ☒ New Pharmacy<br>☐ Ownership Change*<br>☐ Location Change *<br>☐ Name Change*<br><br>* If making a change, provide license #:<br><br>PH_____ | ☒ Retail/Community<br>☐ Hospital (# beds _____)<br>☐ Internet<br>☐ Nuclear<br>☐ Other: | ☒ Retail/Community<br>☒ Non-sterile Compounding<br>☒ Sterile Compounding<br>☒ Mail-Order Service<br>☐ Off-site Cognitive Services<br>☐ Long Term Care<br>☐ Hospital<br>☒ Other:<br>veterinary only |

| Days of Operation | | Ownership Type (check applicable box) |
|---|---|---|
| ☒ Monday | ☒ Friday | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12) |
| ☒ Tuesday | ☐ Saturday | ☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12) |
| ☒ Wednesday | ☐ Sunday | ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12) |
| ☒ Thursday | ☐ Holidays | ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12) |

### Section 1: General Information

Pharmacy Name: Brava NC LLC

Physical Address: 3800 Gateway Centre Blvd

City: Morrisville State: NC Zip: 27560

Mailing Address (if different from physical address): same as above

City: _____ State: _____ Zip: _____

Telephone: (919) 586-8287 Toll Free # (NAC 639.708, NRS 639.23286): 833-901-3600

Fax: (919) 586-8387 Contact Email: brvlicensing@bluerabbit.vet

Website: www.bravacare.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Natalie Young

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23384

**Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)**

| | |
|---|---|
| Name: Tanner Trantham | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |

| Section 3: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✔ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction? | | ✔ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry? | | ✔ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✔ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✔ |

**If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.**

**Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)**

| | | |
|---|---|---|
| Name: N/A | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

**Section 5: Publicly Traded Corporation**

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 6: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: Delaware

Parent Company (if any): RVP Holdco LLC

Corporation/Organization Name: Brava NC LLC

Mailing Address: 2 Union St. Suite 500

City: Portland State: ME Zip: 04101

Telephone: 833-206-4460 Email: brvlicensing@bluerabbit.vet

Contact Person Name: Ann Randall

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ■ No

**Section 7: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 8: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

**Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)**

## Statement of Responsibility

1. I am the President (title) for Brava NC LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

JOEL HERRERA

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

3/7/23

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joel Heberlein

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

Date 3/7/23

| Board Use Only | Date Received: 4.11.23 | Amount: 500.00 CK-100064 |
|---|---|---|

## Officers for Pharmacy and Parent Company

**Brava NC LLC**

Joel Heberlein, President, Treasurer, Secretary
2 Union Street, Suite 500
Portland, ME. 04101

Home Address: [redacted]Damon's Point Circle
Marshfield, MA. 02050

SSN: [redacted]

Phone #: [redacted]

DOB: [redacted]

**RVP Holdco LLC**

Joel Heberlein, President, Treasurer, Secretary
2 Union Street, Suite 500
Portland, ME 04101

Home Address: [redacted]Damon's Point Circle
Marshfield, MA. 02050

# Delaware

The First State



*I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "BRAVA NC LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TENTH DAY OF MARCH, A.D. 2023.*

*AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.*

Jeffrey W. Bullock, Secretary of State

6306053 8300

SR# 20230945971

Authentication: 202889076

Date: 03-10-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

State of Delaware
Secretary of State
Division of Corporations
Delivered 04:00 PM 06/23/2022
FILED 04:00 PM 06/23/2022
SR 20222810167 - File Number 6306053

# STATE OF DELAWARE
# CERTIFICATE OF AMENDMENT

1. Name of Limited Liability Company: RVP LLC

2. The Certificate of Formation of the limited liability company is hereby amended as follows:

FIRST: The name of the limited liability company is: Brava NC LLC.

3. The amended name is to become effective as of June 28th, 2022.

**IN WITNESS WHEREOF**, the undersigned have executed this Certificate on the 23rd day of June, A.D. 2022.

By: _____
Authorized Person(s)

Name: Joel Heberlein
Print or Type

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (04/22/2021)

**Section 1: Pharmacy/Wholesaler Information**

Name of Pharmacy/Wholesaler Brava NC LLC

Physical Address 3800 Gateway Centre Blvd., Suite 308-A

City Morrisville State NC Zip 27560

Mailing Address (if different from physical address) same as above

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

**Section 2: Personal Information**

First Natalie Middle Walters Last Young

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ■ F ☐ X

Mailing Address [redacted] Davis Street

City Raleigh State NC Zip 27608

Telephone [redacted] Email Natalie.young@bravacare.com

Are you a citizen of the United States? ■ Yes ☐ No

| **Section 3: Military Service (NRS 622.120)** | **Yes** | **No** |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/Reserves ☐ Navy/Reserves ☐ Airforce/Reserves ☐ Marine Corps/Reserves ☐ Coast Guard/Reserves ☐ National Guard

| **Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)** | **Yes** | **No** |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | N/A | |



Applicant's initials MY

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| University of North Carolina at Chapel Hill Eshelman School of Pharmacy | | 08/12 - 05/16 | |
| **Address** | **City** | **State** | **Zip** |
| 301 Pharmacy Ln | Chapel Hill | NC | 27599 |
| **Diploma/Degree obtained, if any** | | | |
| Doctorate of Pharmacy | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| University of North Carolina at Chapel Hill | | 08/02 - 05/06 | |
| **Address** | **City** | **State** | **Zip** |
| | Chapel Hill | NC | 27599 |
| **Diploma/Degree obtained, if any** | | | |
| Bachelor of Chemistry | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| North Carolina School of Science and Mathematics | | 08/00 - 06/02 | |
| **Address** | **City** | **State** | **Zip** |
| 1219 Broad St | Durham | NC | 27705 |
| **Diploma/Degree obtained, if any** | | | |
| Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 10/16 - present | [redacted] Davis St | Raleigh | NC | 27608 |
| 08/12 - 10/16 | [redacted] Crafton Way | Raleigh | NC | 27607 |
| 08/07 - 08/12 | [redacted] Washington St | Raleigh | NC | 27605 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Brava NC LLC (formerly RVP LLC) | | | 01/22 - present |
| **Business Address** | **City** | **State** | **Zip** |
| 3800 Gateway Centre Blvd Ste 308A | Morrisville | NC | 27560 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| 919-586-8287 | Pharmacist-In-Charge | 40 / week | |

**Description of Duties**

Ensure adherence to facility SOPs and procedures, adherence to state and federal regulations, and directly supervise all staff.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Realo Veterinary Pharmacy / Realo Drugs | | | 01/20 - 01/22 |
| **Business Address** | **City** | **State** | **Zip** |
| 3800 Gateway Centre Blvd Ste 308A | Morrisville | NC | 27560 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| 919-586-8287 | Pharmacist-In-Charge | 40 / week | |

**Description of Duties**

Ensure adherence to facility SOPs and procedures, adherence to state and federal regulations, and directly supervise all staff.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Realo Veterinary Pharmacy / Realo Drugs | | | 03/17 - 01/20 |
| **Business Address** | **City** | **State** | **Zip** |
| 1301 Commerce Drive | New Bern | NC | 28562 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| 252-636-1711 | Veterinary Director | 40 / week | |

**Description of Duties**

Ensure adherence of all SOPs and procedures related to veterinary program, adherence to state and federal regulations, and directly supervise all veterinary pharmacy operations.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Hardy-White Pharmacies | | | 06/16 - 03/17 |
| **Business Address** | **City** | **State** | **Zip** |
| 1801 Glenwood Ave | Raleigh | NC | 27608 |
| **Phone** | **Title** | **Number of Employed Hours** | |
| 919-835-0457 | Pharmacist Fellow | 30 / week | |

**Description of Duties**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | **Number of Employed Hours** | |
| | | | |

**Description of Duties**

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | N/A | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

Applicant's initials MY

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # _____. **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

Date 3/15/23

Applicant's initials MY

I, Natalie Young, **certify that as the designated representative for** Brava NC LLC,

**that I am qualified as follows and will comply with the following:**

1. I am at least 21 years of age;
3. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. I will serve in this representative capacity for only one pharmacy or wholesaler at a time

Natalie Young

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/15/23

Date

Applicant's initials NY

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Natalie Young

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date 3/29/23

---

**Please have this section completed in the presence of a Notary Public.**

State of Maine, ss. County of Cumberland

I, Natalie Young, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

**Date** 3/29/23

Subscribed and Sworn to before me this 29 day of March 2023

**Notary Public Signature**

NASRO ALI
Notary Public - Maine
My Commission Expires Feb 2, 2029

**(Seal)**

Applicant's initials NK

# Nevada State Board Of Pharmacy

(Licensee mailing address for window envelope)

THIS STUB IS YOUR RECEIPT

Date: 01/09/2023
Amount:
License #: 23384

Natalie W. Young

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Pharmacist
Effective Date:01/09/2023
Expires:10/31/2023

Natalie W. Young

License #
23384
Active

IDENTIFICATION ONLY
DOES NOT MEET POSTING REQUIREMENTS

Trim ID Card to fit your wallet

Cut Here

NEVADA
STATE BOARD OF PHARMACY
Pharmacist

Expires: 10/31/2023
STATUS: Active

License Type: Pharmacist
License #: 23384
Effective Date:01/09/2023

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENSED

Natalie W. Young

**NONTRANSFERABLE**

POST THIS LICENSE PROMINENTLY IN A CONSPICUOUS PLACE

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

### Section 1: General Information

Pharmacy Name: Brava NC LLC

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 3800 Gateway Centre Blvd., Suite 308-a

City: Morrisville State: NC Zip: 27560

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 919-586-8287 Toll Free # (NAC 639.708, NRS 639.23286): 833-901-3600

Fax: 919-586-8387 Contact Email: brvlicensing@bluerabbit.vet

Website: www.bravacare.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Natalie Young

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23384

Name of Person with direct knowledge of compounding procedures: Natalie Young

Email of Person with direct knowledge of compounding procedures: natalie.young@bravacare.com

Telephone of Person with direct knowledge of compounding procedures: 919-586-8287

**Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)**

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☐ Low ☐ Medium ☑ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☑ Yes ☐ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
Apomorphine 1mg/mL Injectable
Apomorphine 2mg/mL Injectable
Cyclosporine 1% Ophthalmic Solution
Cyclosporine 2% Ophthalmic Solution
Tacrolimus 0.03% Ophthalmic Solution

4. Will you be utilizing beyond use dates in excess of USP-797? ☑ Yes ☐ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:
Each product has a stability study performed at an analytical lab (ex. ARL, Eagle Analytical, CIAL) with testing to support the extended BUD. Testing for appearance, container closure, particulate matter, potency, and sterility were performed at various time points to determine the BUD for each product. These full reports are available upon request.

6. What laboratory performs this additional testing?

Name: ARL Biopharm Infinity Laboratories Eagle

Address: 840 Research Pwyy Suite 546 1585 South Perry St Suite B 9940 W. Sam Houston Pkwy Suite 310

City: Oklahoma City Castle Rock Houston State: OK, CO, TX Zip:

Telephone: (405) 271-1144 303-730-7330 832-295-1276

7. What is your procedure for visual inspection of compounded sterile products?
Each sterile product is visually inspected for container leaks, integrity, cloudiness/separation, appropriate color/odor, appropriate volume/viscosity, and particles.

8. How often do you perform glove fingertip and medial fill testing?
Brava follow USP <797> guidance on fingertip and media fill testing. Sterile compounding personnel must perform a high-risk media fill every 6 months and a low/medium risk media fill every 12 months. A post garb and post compounding fingertip sample must be performed on each hand for each media fill.

9. What is your policy if an employee fails a glove fingertip or media-fill test?
Personnel who fail must undergo re-training and re-evaluation by qualified personnel prior to resuming sterile compounding.

10. Describe your initial and annual training program for all personnel performing sterile compounding:
In addition to the sterile competency assessments listed above for #8, a review of USP 797 and aseptic technique must be performed prior to performing sterile compounding or checking sterile compounding preparations, at least every 6 months thereafter and upon evidence of poor technique. A written didactic quiz must be completed to document understanding. Retraining is required for scores < 80%.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
PEC: Deactivate, decontaminate , clean, and disinfect from cleanest to dirtiest (i.e. top to bottom and back to front) at the beginning of each shift (and the area under the work surface (if applicable) at least monthly). Document on Cleaning and Calibration Log (Attachment 1) or equivalent log. Decontaminate and disinfect the work surface of the C-PEC before each batch preparation, every 30 minutes during continuous compounding, when spills occur and when surface contamination is known or suspected.The C-PEC must also be decontaminated before and after certification, any time it is turned off, and any time it is moved. Sporicide must be used at least monthly. SEC: Deactivation, decontamination, cleaning, and disinfection must not occur at the same time as compounding. Work surfaces, sink, and floors are daily. Ceiling, walls, and storage areas/carts are monthly.

Agents used are Peridox RTU, PreEmpt Plus, and IPA 70%

12. Who performs the sterile compounding process at your facility?
Tanner Trantham - pharmacist

13. Who is responsible and accountable for the sterile compounding process at your facility?
Natalie Young (PIC) and Tanner Trantham (Pharmacist)

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
Compounded preparations shall be properly packaged to preserve quality, strength, purity, integrity and sterility. Packages should protect compounded preparations from temperature extremes, physical damage and light. HDs should be enclosed in a sealed plastic bag. Temperature verification testing shall be performed at least every six months to ensure packages shipped at room temperature are maintaining required temperature ranges.Excursions between 15° and 30° C during shipping are allowed, provided the mean kinetic temperature does not exceed 25° C. Transient spikes up to 40° C are permitted as long as they do not last for more than 24 hours. Spikes above 40° C may be permitted only if the manufacturer so instructs. Mailed compounded preparations that require refrigeration shall be packaged in a styrofoam cooler (or equivalent packaging) with ice packs. A temperature indicator card (showing exposure above 46F) shall be included in each package unless a validated shipping method is used and verified at least every six months.

**Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)**

1. What type of primary engineering controls will you be using in your facility?
Biological Safety Cabinet

| | | |
|---|---|---|
| 2. Is your BSC or CACI vented 100% to the outside? | ☑ Yes | ☐ No |
| 3. Do you have a negative pressure buffer room at your facility? | ☑ Yes | ☐ No |
| 4. Will you be compounding with antineoplastic HDs or HD API? | ☑ Yes | ☐ No |
| 5. If yes, are the drugs stored in an externally ventilated, negative pressure room? | ☑ Yes | ☐ No |
| 6. Will you be utilizing a closed system transfer device? | ☐ Yes | ☑ No |

7. If yes, list the name of the device:
N/A

8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?
For each new HD prescription, a printed medication guide is provided to the client to inform the client about any handling and disposal concerns they may have once the medication is received. The pharmacist also appropriately educates the client during the initial contact on any precautions/warnings warranted for that particular hazardous drug.

9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?
All personnel who handle HDs or who perform custodial waste removal or cleaning activities must be trained based on their job functions (e.g., in the receipt, storage, compounding, repackaging, dispensing, and disposing of HDs). Training must occur before the employee independently handles HDs. The effectiveness of training for HD handling competencies must be demonstrated by each employee. Personnel competency must be reassessed at least every 12 months. Personnel must be trained prior to the introduction of a new HD or new equipment and prior to a new or significant change in process or SOP. All training and competency assessment must be documented. The training must include at least the following: overview of entity's list of HD drugs and their risk; review of SOPs related to HDs, proper use of PPE, proper use of equipment and devices, prevention of HD contamination, spill management and use of a spill kit, response to known or suspected HD exposure, and proper disposal of HDs and trace-contaminated materials.

**Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)**

1. List the specific high risk sterile products that your facility compounds:

Apomorphine 1mg/mL Injectable
Apomorphine 2mg/mL Injectable
Cyclosporine 1% Ophthalmic Solution
Cyclosporine 2% Ophthalmic Solution
Tacrolimus 0.03% Ophthalmic Solution

2. What sterilization methods are utilized at your facility?

Each compound is filtered using a 0.22 micron filter into its final dispensing container. Then, based on the batch size, the appropriate number of containers are sent off for sterility and endotoxin (if applicable) testing. Our facility also uses a convection oven to sterilize any necessary equipement for the compounding process.

3. Does your facility utilize biological indicators? ☑ Yes ☐ No

4. If yes, describe how they are utilized:

Prior to making our sterile compounded preparations, the glassware and stir bars are sterilized and depyrogenated using a dry heat convection oven. Biological indicators are placed inside each cycle and incubated to validate the effectiveness of each cycle. An endotoxin challenge test is performed annually to ensure that the oven and process is capable of achieving a 3-log reduction in endotoxin.

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Natalie Young
Name of Person who Completed the Form

Pharmacist in Charge
Title

Signature (copies or stamps not accepted)

11/17/22
Date

| Board Use Only | Date Received: 4/1/23 Date Approved: _____ Approved By: _____ |
|---|---|

North Carolina Board of Pharmacy

Enforcement v220222

## Inspection Details

| | | | | | |
|---|---|---|---|---|---|
| **Name** | RVP | **Case #** | | **Permit** | 14867 |
| **Address** | 3800 Gateway Centre Blvd Morrisville, NC 27560 | **Person Providing Info** | Natalie Young and Tanner | **Inspection Date** | 03/23/2022 |
| | | **Person In Charge** | Natalie Walters Young | **Inspection User** | Stefanyk, Krystal |
| | | | | **Inspection District** | DISTRICT3 |
| **# RPhs** | 2 | **Rx Volume/Date** | | | |
| **# Techs** | 6 | **Hours** | 8-5 M-F | | |
| **Follow-Up CAP** | No | **Office** | Yes | | |
| **CAP Requested** | No | **Commercial Use** | No | | |
| **CAP** | No | **Ship to Other States** | No | | |
| **Documentation Received** | | **States Shipped To** | | | |
| **Non-Sterile Compounding Levels** | Simple, Moderate, Complex, Hazardous | | | | |
| **Sterile Compounding Levels** | Medium, High, Hazardous | | | | |

## Pharmacy Staffing

**What is the P:T ratio at the time of inspection:** 2:4

**If ratio is above 1:2 at the time of inspection, how many certified technicians are on shift:**

5 certified technicians

**What is the approved Pharmacist: Technician ratio?**

**How often is there only one pharmacist on duty:** Usually 2 on duty

**How many technicians are usually on shift at a time:** 4 on duty

**Are pharmacists asked to do any duties outside of the pharmacy :**

NA

## Pharmacy Volume

**Does pharmacy administer vaccines:** No

**What is the daily average of vaccines:**

**What staff members are administering vaccines and what type of vaccines:**

**How far behind is the pharmacy on filling and verifying prescriptions:**

NA

**How long has this backlog persisted:** NA

**Does pharmacy conduct any point of care testing such as COVID:**

No

**What is the daily average of testing:**

**What staff is responsible for administering test and what is testing procedure:**

**Are administered vaccines reported to the appropriate vaccine registry:**

**In your opinion is the rate you are dispensing per hour or per day safe or does it pose a threat to public health and safety:**

yes safe.

## Comments

Pharmacy is solely veterinary compounding.

The pharmacy has a pharmacist on-call for after hours and on weekends to field patient concerns or questions.

The pharmacy either ships or delivers medications via delivery driver to the patients. The pharmacy is open door, so patients can pick medication up at the pharmacy as well, but that happens very seldom.

The pharmacy has a non-sterile hazardous negative pressure room to store hazardous non-sterile APIs and to make hazardous non-sterile preparations.

The pharmacy has an ISO 8 anteroom that leads into another IS0 7 anteroom. The ISO 7 anteroom leads into a negative pressure cleanroom, which has a BSC that maintains ISO 5. Also in that room is another BSC for weighing out hazardous non-sterile powders for sterile preparations. The ISO 7 anteroom also leads into a positive pressure cleanroom, which does not currently house a PEC.

Pharmacy currently only compounds two sterile products, Cyclosporine ophthalmic and Tacrolimus ophthalmic. Both have a stability indicating assay and are sterility tested with each batch. The pharmacy use ARL for sterility testing of hazardous high risk sterile preparations. The pharmacy currently uses ARL for potency testing and stability testing on some non-sterile preparations.

## General Pharmacy Regulations

| | Answer | Question |
|---|---|---|
| 1) | Satisfactory | NCGS 90-85.15A (a) - tech must register with the Board within 30 days after the date of completing the training program. |
| 2) | Satisfactory | NCGS 90-85.15A (c) - 2:1 ratio, if ratio above provide waiver documentation. Any technician above the 2:1 ratio must be certified. |
| 3) | Satisfactory | NCGS 90-85.23- PM license, permit and current renewal shall be posted. Licenses and renewals of each RPh. are readily available for inspection. |
| 4) | Satisfactory | NCGS 90-85.25 (b) - PM shall report within 10 days any disaster, accident, theft. |
| 5) | Satisfactory | NCGS 90-85.26 (a) - prescriptions preserved for 3 years. (b) - Documentation of alleged medication errors. |
| 6) | Satisfactory | NCGS 90-85.29 (1) - prescription label shall contain a discard date that is earlier of 1 yr. from date dispensed or manuf's exp. date, whichever is earlier. (2) - not obscure exp. date and storage statement when product dispensed in manuf's original container. |
| 7) | Satisfactory | NCGS 90-85.32 (a) - prescriptions marked PRN not refilled more than 1 yr. after issue date. |
| 8) | Satisfactory | NCGS 90-85.47 - Quality Assurance Program |
| 9) | Not Applicable | NCGS 90-93 (3)(d): Sch. V log book or record of disposition. |
| 10) | Not Applicable | NCGS 90-106.1 (a) - documentation system of photo ID. Kept on premises or central location for 3 years. |
| 11) | Not Applicable | NCGS 90-113.52 (b) - pseudoephedrine Products kept behind counter. (c) - record of every purchaser, amount of product in grams. (d) - records kept for two 2 years. |
| 12) | Not Applicable | NCGS 90-113.54 - posting of sign prohibiting sale of more than 2 pkgs (3.6grams total) of pseudoeph. /day, no more than 3 pkgs (9grams total) within 30- day period. |
| 13) | Satisfactory | NCGS 90-640 (b) - ID badge |
| 14) | Satisfactory | 21CFR 201.17- Misbranded drugs: Medications stored in pharmacy should be labeled with an expiration date and manufacturer lot number. Note: Return to stock prescription vial with the pharmacy's own label affixed will not be deemed misbranded |
| 15) | Satisfactory | 21 NCAC 46.106-134.1 (4)(b)- label lacks any requirement listed in the subsection. (px name, name/add. of pharmacy, disp. rph's name, rx #, fill date of rx, prescriber name, dir. for use, name & strength of drug.) |
| 16) | Satisfactory | 21 NCAC 46.1601 (a)(2)- posted Pharmacy hours. (4)(A-E)- reference library, hard copy or electronic. (5)- lavatory facilities w/ hot and cold running water; clean, orderly and sanitary. (b)(1)- records are readily retrievable. (b)(2)- toll free number on labels of dispensed medications. (e)- pharmacy permit is countersigned by rphmgr. as represented in the application. |
| 17) | Satisfactory | 21 NCAC 46.1802 (a) - refills limited to prescriber's orders. |
| 18) | Satisfactory | 21 NCAC 46.1803 - All records pertaining to the filling and refilling of prescriptions shall be available to designated employees of the Board during normal business hours. |
| 19) | Satisfactory | 21 NCAC 46.1806 - proper documentation and handling of transferred rxs |
| 20) | Satisfactory | 21 NCAC 46.1818 - label shall list generic name of drug, even if unavailable to dispense or generic is not authorized. |
| 21) | Satisfactory | 21 NCAC 46.2302 (a)(1-5) - records of dispensing shall be kept for 3 years. |
| 22) | Satisfactory | 21 NCAC 46.2303 - records of prescription filling and refilling shall be kept for 3 yrs. |
| 23) | Satisfactory | 21 NCAC 46.2304 (1) - produce sight-readable documents. (3) - RPh. responsible for completeness and accuracy of entries, provides documentation that prescription information entered is correct. (5) - pharmacy has auxiliary recordkeeping system. (7) - current version of drug interactions software is utilized |
| 24) | Satisfactory | 21 NCAC 46.2305 - To maintain the confidentiality of patients' prescription orders, there must be adequate safeguards or security of the records. |
| 25) | Satisfactory | 21 NCAC 46.2502 (a) - PM shall assure that rx meds & cs meds are safe/secure within the pharmacy. (b) - PM is present one-half the hrs. the pharmacy is open or 32 hrs. /wk., whichever is less. (d) - system of inventory recordkeeping and control to detect any shortage or discrepancies of cs meds. (e) - control of all keys to pharmacy. (j) - written disaster plan. (k) - separate from the dispensing stock all drugs more than 6 months out of date. |
| 26) | Satisfactory | 21 NCAC 46.2504 (a) - effective communication of information to the patient(s). (b) - offer to counsel for all new and transfer prescriptions. (g) - Documentation of refusals. |
| 27) | Satisfactory | 21 NCAC 46.3001 (a) - policy/procedure for all out dated, improperly labeled, adulterated damaged or |

| General Pharmacy Regulations | | |
|---|---|---|
| | **Answer** | **Question** |
| | | unwanted drugs or drug containers are destroyed or disposed. |
| 28) | Satisfactory | 21 NCAC 46.3301 (b) - Current registration of a pharmacy tech shall be readily available for inspection. |
| 29) | Satisfactory | 21CFR 1301.75 (b) - controlled substances listed in II, III, IV, and V shall be stored in a substantially constructed cabinet, or disbursed throughout the non-controlled substances |
| 30) | Satisfactory | 21CFR 1304.04 (2)(h)(1) - inventories and records of Sch. I & II substances maintained separate from all other records (2)(h)(2)- paper prescriptions for Sch. II substances maintained in separate file. |
| 31) | Satisfactory | 21CFR 1304.11 (a) - complete/accurate inventory of all cs meds and maintained at the registered location. (c) - Biennial inventory. |
| 32) | Satisfactory | 21CFR 1305.05 (a) - power of attorney on file at registered location. |
| 33) | Satisfactory | 21CFR 1305.12 (b) - purchaser shall record 1 item on each numbered line. (c) - name/address of supplier on form. Only 1 supplier on any form. (d)- DEA Form 222 properly signed and dated. |
| 34) | Satisfactory | 21CFR 1305.13 (e) - purchaser must record the number of commercial or bulk containers furnished on each item and dates on which the containers are received. |
| 35) | Satisfactory | 21CFR 1305.22 Procedure for filling electronic orders. (g) - purchaser receives shipment, purchaser must create a record of the quantity of each item received and date received. Record must be electronically linked to the original order and archived. |
| 36) | Satisfactory | 21CFR 1305.27 Preservation of electronic orders. (a) purchaser must, for each order filled, retain the original signed order and all linked records for that order for 2 years. Purchaser must also retain all copies of each unaccepted or defective order and each linked statement. (b) supplier must retain each original order filled and the linked records . (Note: 2yrs for Federal Law; 3yrs for NC Law) (c) If electronic order records are maintained on a central server, records must be readily retrievable at the registered location. (Note: 2yrs for Federal Law; 3yrs for NC Law) |
| 37) | Satisfactory | 21CFR 1306.05 (a) - all cs prescriptions shall bear full name and address of the patient along with date, drug, strength, dosage form, quantity, dirs. for use, and name, address and registration number of practitioner. (d) - computer generated prescription that is printed or faxed must be manually signed |
| 38) | Satisfactory | 21CFR 1306.08 (3)(b) - pharmacy may fill electronically transmitted prescription for a cs med provided the pharmacy complies with all requirements. A Sch. II order signed by the prac- titioner. |
| 39) | Satisfactory | 21CFR 1306.14 (a) - prescription vials labeled for Sch. II display pharmacy name and address, rx #, initial fill date, patient name, practitioner name, dirs. for use and any cautionary statements. |
| 40) | Satisfactory | 21CFR 1306.21 (a) - order for Sch. III, IV, or V that is a facsimile is signed by practitioner. |
| 41) | Satisfactory | 21CFR 1306.22 (b) - cs refills entered on a medication record or electronic record must be uniformly maintained and readily retrievable. |
| 42) | Satisfactory | 21CFR 1306.24 (a) - prescription vials labeled for Sch. III, IV, or V display pharmacy name and address, rx #, initial fill date, patient name, practitioner name, dirs. for use and any cautionary statements. |
| 43) | Not Applicable | 21CFR 1306.26 (b) - not more than 8oz. of any cs containing opium, nor more than 4oz. of any other cs; not more than 48 dosage units of any such cs containing opium, nor more than 24 dosage units of any other such cs to the same purchaser in any 48-hr. period. (c) - purchaser at least 18 yoa (d) - furnish suitable ID (e) - maintain log containing name and address of purchaser, name and qty. of cs, date of purchase, name or initials of RPh. who dispensed the substance. |
| 44) | Satisfactory | 21CFR 1311.10 Eligibility to obtain a CSOS digital certificate. (a) - person who signed the most recent DEA registration application or renewal application and a person authorized to sign a registration application. (b) - person granted power of attorney by a DEA registrant to sign orders for one or more schedules of controlled substances. |
| 45) | Satisfactory | 21CFR 1311.30 Requirements for storing and using a private key for digitally signing orders. (a) - Only the certificate holder may access or use his or her digital certificate and private key. (b) - The certificate holder must provide FIPSapproved secure storage for the private key, as discussed by FIPS 140-2, 180-2, 186-2, and accompanying change notices and annexes, as incorporated by reference in §1311.08. (c) - A certificate holder must ensure that no one else uses the private key. While the private key is activated, the certificate holder must prevent unauthorized use of that private key. |
| 46) | Satisfactory | 21CFR 1311.35 Number of CSOS digital certificates needed. A purchaser of Schedule I and II controlled substances must obtain a separate CSOS certificate for each registered location for which the purchaser will order these controlled substances. |
| 47) | Satisfactory | 21CFR 1311.60 Recordkeeping. (a) - supplier and purchaser must maintain records of CSOS electronic orders |

## General Pharmacy Regulations

| | Answer | Question |
|---|---|---|
| | | and any linked records for 2 years. Records may be maintained electronically. Records regarding controlled substances that are maintained electronically must be readily retrievable from all other records. (Note: 2yrs for Federal Law; 3yrs for NC Law) (b) - Electronic records must be easily readable or easily rendered into a format that a person can read. Must be made available to the Administration upon request. (c) - CSOS certificate holders must maintain a copy of the subscriber agreement that the Certification Authority provides for the life of the certificate. |

## Simple Compounding/Occasional Basic Non-Sterile Compounding

| | Answer | Question |
|---|---|---|
| 1) | Satisfactory | Occasional Basic Non-Sterile Compounding means combining one or more conventionally manufactured products pursuant to an individual prescription on an occasional basis. This includes but is not limited to: Magic Mouthwash, GI Cocktail, creams or ointments using only conventionally manufactured products. |
| 2) | Satisfactory | a) Official name, strength, and dosage of preparation. |
| 3) | Satisfactory | b) Name and quantities of all components. |
| 4) | Satisfactory | c) Sources, lot numbers, and expiration dates of components. |
| 5) | Satisfactory | d) Name of person who compounded and the person verified the preparation. |
| 6) | Satisfactory | e) Date preparation. |
| 7) | Satisfactory | f) Assigned BUD. |
| 8) | Satisfactory | g) Description of final preparation. |
| 9) | Satisfactory | h) Description of Compounding Steps |

## Non-Sterile

| | Answer | Question |
|---|---|---|
| 1) | Satisfactory | **Simple:** Making a preparation that has a USP compounding monograph or appears in a peer reviewed journal that contains specifics on component quantities, compounding procedure, equipment and stability data for the formulation and appropriate Beyond Use Dates (BUD), or Reconstituting or manipulating commercial products that require addition of one or more ingredients as directed by the manufacturer. **Examples of Non-Sterile Compounding:** Captopril Oral Solution, Indomethacin Topical Gel and Potassium Bromide Oral Solution |
| 2) | Satisfactory | **Moderate:** Compounding a preparation that requires special calculations or procedures to determine quantities of components per preparation or per dosage unit. Making a preparation for which stability data is not available for the preparation. **Examples of Moderate Non-Sterile Compounding:** morphine sulfate suppositories, diphenhydramine troches, or mixture of two or more manufactured creams when stability of the mixture is not known. |
| 3) | Satisfactory | **Complex:** Making a preparation that requires special training, environment, facilities, equipment and procedures to ensure appropriate therapeutic outcomes. **Examples of Complex Non-Sterile Compounding:** transdermal dosage forms, modified-release preparations and suppositories for systemic effects. |
| 4) | Satisfactory | **Hazardous or NIOSH listed:** Any drug identified as carcinogenic, teratogenic, reproductive toxicity, organ toxicity, genotoxicity or any new drug that mimics existing hazardous drugs in structure or toxicity. These drugs are identified in the National Institute for Occupational Safety and Health (NIOSH) publication list. |
| **Personnel Training** | | |
| 5) | Satisfactory | Documentation that all personnel that perform compounding are appropriately trained including policy and procedures, compounding documentation, Hazardous drug handling, and compounding technique. This includes pharmacist manager or designated pharmacist |
| 6) | Satisfactory | Documentation that the training includes the operation of any equipment that may be used when preparing compounded products. |
| 7) | Satisfactory | Documentation showing the employee has been trained on the storage, handling, and disposal of Hazardous Drugs. |
| 8) | Satisfactory | Documentation that the training process for the preparation of compounds include demonstration of the compounding procedures, calculations, and finished preparation before being allowed to preform compounding. |
| **Components Selection** | | |
| 9) | Satisfactory | Are Certificates of Analysis (COA) obtained and reviewed for all bulk APIs used for compounding |

| Non-Sterile | | |
|---|---|---|
| | **Answer** | **Question** |
| 10) | Satisfactory | Are USP or NF grade components used, if available. |
| 11) | Satisfactory | If USP– NF components are not available does pharmacy use components that are chemically pure, analytical reagent grade, or American Chemical Society certified. |
| 12) | Satisfactory | All substances or components labeled with a batch control number or lot number, and an expiration date. |
| 13) | Satisfactory | Components that do not have an expiration date are labeled with date received and a conservative expiration date that does not exceed three years. |
| 14) | Satisfactory | Hazardous Bulk components segregated (including hormones). |
| 15) | Satisfactory | Ingredients used for dietary or nutritional supplements meet USP, Food Chemical Codex (FCC), or NF Standards, or does the pharmacy have alternate means to determine if the ingredients meet food-grade quality. |
| 16) | Satisfactory | Compounded medications for Veterinary application labeled to indicate "Veterinary Use " |
| 17) | Satisfactory | There are no preparations made or ingredients used that appear on the FDA list of drugs products withdrawn or removed from the market for safety reasons. |
| Beyond Use Dating | | |
| 18) | Satisfactory | Documentation on Compounding record of BUD assigned |
| 19) | Satisfactory | Compliance with USP 795: A) For Non aqueous Formulations— the BUD is not later than the time remaining until the earliest expiration date of any API or 6 months which ever is earlier. B) For Water-Containing Oral Formulations—The BUD is not later than 14 days when stored at controlled cold temperatures C) For Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations—The BUD is not later than 30 days |
| 20) | Satisfactory | If the beyond-use dates are exceeded the pharmacy must have supporting valid scientific stability information that is directly applicable to the specific preparation (i.e., the same drug concentration range, pH, excipients, vehicle, water content, etc.). |
| Master Formulation Records | | |
| 21) | Satisfactory | Official or assigned name, strength, and dosage form of the preparation (ISMP guidelines, no Abbreviations). |
| 22) | Satisfactory | Calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients (API) |
| 23) | Satisfactory | Description of all ingredients and their quantities |
| 24) | Satisfactory | Compatibility and stability information, including references when available |
| 25) | Satisfactory | Equipment needed to prepare the preparation, when appropriate |
| 26) | Satisfactory | Mixing instructions that should include: a. order of mixing b. mixing temperatures or other environmental controls c. duration of mixing d. other factors pertinent to the replication of the preparation as compounded |
| 27) | Satisfactory | Sample label information, which shall contain, in addition to legally required information: a. generic name and quantity or concentration of each active ingredient b. assigned BUD c. storage conditions d. prescription or control number, whichever is applicable. |
| Compounding Record | | |
| 28) | Satisfactory | Container used in dispensing |
| 29) | Satisfactory | Packaging and storage requirements |
| 30) | Satisfactory | Description of final preparation |
| 31) | Satisfactory | Quality control procedures and expected results |
| 32) | Satisfactory | Official or assigned name, strength, and dosage form of the preparation; (ISMP guidelines no Abbreviations). |
| 33) | Satisfactory | Master Formulation Record reference for the preparation . |
| 34) | Satisfactory | Names and quantities of all components. |
| 35) | Satisfactory | Sources, lot numbers, and expiration dates of components. |
| 36) | Satisfactory | Total quantity compounded. |
| 37) | Satisfactory | Name of the person who prepared the preparation, name of the person who performed the quality control procedures, and name of the compounder who approved the preparation. |
| 38) | Satisfactory | Date of preparation. |
| 39) | Satisfactory | Assigned control or prescription number. |

| Non-Sterile | | |
|---|---|---|
| | **Answer** | **Question** |
| 40) | Satisfactory | Assigned BUD |
| 41) | Satisfactory | Duplicate label as described in the Master Formulation Record. |
| **Compounding Environment** | | |
| 42) | Satisfactory | Results of QC procedures documented (weight range of filled capsules, pH of aqueous liquids, etc). |
| 43) | Satisfactory | Compounding Facility has adequate space that is specifically designated for compounding prescriptions. Space allows for orderly placement of equipment and only one compound at a time. |
| 44) | Satisfactory | Procedures are implemented to prevent cross– contamination, especially when compounding with drugs such as hazardous drugs and known allergens like penicillin that require special precautions. |
| 45) | Satisfactory | The compounding area is well lit. |
| 46) | Satisfactory | Pharmacy perform hazardous non-sterile compounding in a ventilated cabinet (Powder Containment Hood). |
| 47) | Satisfactory | Ventilated Cabinet (Powder Containment Hood) certified or tested according to manufacturer specifications. Documentation required. |
| 48) | Satisfactory | Hood prefilters are checked and replaced regularly. |
| 49) | Satisfactory | Pharmacy has sink located in the compounding area with hot and cold water, soap or detergent, air-driers or single use towels |
| 50) | Satisfactory | Pharmacy has adequate space to wash equipment and utensils including access to water for rinsing. |
| 51) | Satisfactory | Appropriate temperature and humidity monitors maintained and documented. |
| 52) | Satisfactory | Bulk ingredients stored in a clean and sanitary condition. |
| 53) | Satisfactory | Appropriate protective attire (gloves, gowns, mask, etc) are available including appropriate PPE for Hazardous Drug Compounding. (See NIOSH alert) |
| 54) | Satisfactory | Hazardous drugs are stored, prepared, and handled by appropriately trained personnel under conditions that protect the health care worker and other personnel (OSHA regulations and NIOSH Alert). |
| 55) | Satisfactory | Trash is disposed of in a safe and sanitary manner in accordance with state and federal regulations including Hazardous waste. |
| **Compounding Equipment** | | |
| 56) | Satisfactory | Utensils used for compounding are neither reactive nor additive, and therefore will not affect or alter the purity of the compounded preparation. |
| 57) | Satisfactory | Appropriate equipment and utensils are available and cleaned regularly throughout the compounding process. Appropriate cleaning policies and procedures followed. |
| 58) | Satisfactory | Scales, balances, or other equipment used for measurement are validated and calibrated at least annually. (See USP 1176) |
| 59) | Satisfactory | The pharmacy uses separate equipment and utensils to compound allergenic, cytotoxic, or hazardous products, or has detailed procedures for cleaning of equipment and utensils immediately after use to prevent cross-contamination or exposure. |
| **Finished Preparation Release** | | |
| 60) | Satisfactory | Is the finished preparation checked to ensure it appears as expected in the master formulation record. |
| 61) | Satisfactory | Final completed preparations assessed for weight, mixing, clarity, odor, consistency, pH, and strength. This is documented. |
| 62) | Satisfactory | There are established written policies and procedures that describe tests or examinations conducted on the compounded preparation to ensure uniformity and integrity. |
| 63) | Satisfactory | Labels on immediate patient specific container need to include in addition to all legally required elements, identifiers for the person preparing the compound and performing the final verification, BUD, an indication that this is a compound, special storage requirements, and appropriate packing. |
| 64) | Satisfactory | For Batch preparations (in anticipation of prescriptions) are of appropriate volume, labeled with official name, quantity of all contents, date and time of the preparation, preparer, and verifying RPh, the correct BUD, and any auxiliary labels including appropriate packaging and labeling of hazardous materials any auxiliary labels. |
| 65) | Satisfactory | Preparations are stored properly prior to dispensing based upon conditions which BUD was assigned. |
| 66) | Satisfactory | Preparations are examined immediate after preparation and prior to dispensing |
| **Quality Assurance** | | |

## Non-Sterile

| | Answer | Question |
|---|---|---|
| 67) | Satisfactory | Pharmacy has/keeps quality related event reports for compounded products. |
| 68) | Satisfactory | The facility QA program identifies action limits or thresholds and the appropriate follow up mechanism when action limits or thresholds are exceeded including a recall system. |
| 69) | Satisfactory | The pharmacy has a recall system in place to communicate with the patients and physicians regarding affected compounded products. |

## Sterile

| | Answer | Question |
|---|---|---|
| **Facility Design** | | |
| 1) | Not Applicable | PEC ISO 5 in non-controlled room - segregated - 12hr BUD only (Low risk only). |
| 2) | Not Applicable | CAI and CACI placed in an ISO 7 buffer area unless: maintains ISO class 5 during dynamic operations, transfer of ingredients during compounding preparations. |
| 3) | Satisfactory | PEC ISO 5 located in Buffer with anteroom (solid walls) Buffer maintains ISO 7. |
| 4) | Satisfactory | Pressure differential 0.02- 0.05 between rooms - must have magnahelix or pressure gauge & documented daily. |
| 5) | Not Applicable | PEC ISO 5 located in Buffer without anteroom - must have 40 FPM or 0.2 meters/second airflow across line of demarcation (need meter) - only low & medium risk allowed. Needs to be documented. |
| 6) | Satisfactory | No Ledges. |
| 7) | Satisfactory | Buffer area well lighted. |
| 8) | Satisfactory | Maintains comfortable temperature. |
| 9) | Satisfactory | Pre-sterilization area with Powder containment hood for high risk compounding (weighing and measuring) must be ISO 8 with 20 ACPH. NOTE: Must be fully garbed and gloved and garbing and gloving must be changed prior to entering ISO 7 Clean room. Cannot be in Buffer. |
| 10) | Satisfactory | Only the furniture, equipment, supplies and other material required for the compounding activities are brought into the area and they are non-permeable, non-shedding, cleanable, and resistant to disinfectants; before such items are brought into the area, they are cleaned and disinfected. |
| 11) | Satisfactory | Wall to floor coved or caulked to avoid cracks and crevices where dirt can accumulate. |
| 12) | Satisfactory | Buffer area has no sink or floor drain. |
| 13) | Satisfactory | Clean room grade ceiling tiles that are impervious. |
| 14) | Satisfactory | Ceiling tiles caulked. (Note no gaskets) |
| 15) | Satisfactory | Carts are stainless steel wire or solid shelving with cleanroom casters. |
| 16) | Satisfactory | Storage shelving, counters and cabinets are smooth, impervious, free from cracks and crevices, non-shedding, cleanable and disinfectable; their number, design and manner of installation promotes effective cleaning and disinfection. |
| 17) | Satisfactory | The surfaces of ceilings, walls, floors, fixtures, shelving, counters and cabinets in the buffer area are smooth, impervious, free from cracks and crevices and non-shedding; the surfaces are resistant to damage by disinfectant agents. |
| 18) | Satisfactory | No cardboard within the buffer or ante room |
| 19) | Satisfactory | Storage kept at a minimum |
| 20) | Satisfactory | Trash removed on a regular basis with minimal agitation |
| 21) | Satisfactory | Lights have flush mounted smooth surfaces |
| 22) | Satisfactory | Penetrations through walls sealed |
| 23) | Satisfactory | Hazardous compounding in separate room and room negative 0.01 as well as ISO 7 documented daily. |
| 24) | Satisfactory | Anteroom between Positive pressure and negative pressure clean rooms must be ISO 7 |
| 25) | Not Applicable | Low Use Exemption (3 doses per week) BSC or CACI in non negative pressure with the use of a Closed system transfer device. |
| **Cleaning & Disinfecting** | | |
| 26) | Satisfactory | Cleaning and Disinfecting SOP documented |

| Sterile | | |
|---|---|---|
| | **Answer** | **Question** |
| 27) | Satisfactory | Cleanliness of facility is evident, no dust on PEC or other equipment |
| 28) | Satisfactory | PEC cleaned at the beginning of each shift, before each batch, not longer than 30 minutes if on going compounding, after spills, and when surfaces are contaminated with sterile IPA |
| 29) | Satisfactory | Counters and easily cleanable work surfaces cleaned daily |
| 30) | Satisfactory | Floors cleaned daily |
| 31) | Satisfactory | Walls, Ceilings, and storage shelves cleaned monthly |
| 32) | Satisfactory | Use of low shedding wipes. |
| 33) | Satisfactory | Use of Sterile 70 % IPA and appropriate disinfectant . (See USP 1072) |
| **Certification-ACPH/Filter Integrity** | | |
| 34) | Satisfactory | Cleanroom and PEC certifications performed at least every six months. |
| 35) | Satisfactory | Anteroom has 20 ACPH per CETA guidelines. |
| 36) | Satisfactory | Buffer area has 30 ACPH (maximum 15 ACPH can be provided by the PEC). |
| 37) | Satisfactory | HEPA Filters leak tested and documented. |
| 38) | Satisfactory | ACPH measured and documented for all ISO Classified areas. |
| 39) | Satisfactory | PEC HEPA Filter Leak test performed and documented. |
| 40) | Satisfactory | PEC HEPA Filter air velocity testing performed and documented. |
| 41) | Satisfactory | PEC has a dynamic Air pattern Analysis (smoke study) performed and documented. Certification done under dynamic conditions with staff simulating activities. |
| **Environment Monitoring (Non Viable)** | | |
| 42) | Satisfactory | Particle Count of ISO 5 PEC (LAFW,BSC,CAI,CACI) performed every 6 months or more frequently. Note Frequency. |
| | **Comments:** six months | |
| 43) | Satisfactory | Action Level: not more than 3520 particles 0.5 µm and larger size per cubic meter of air for any LAFW, BSC, CAI, and CACI. |
| 44) | Satisfactory | Particulate count of ISO7 buffer performed every 6 months or more frequently. Note frequency. |
| | **Comments:** six months | |
| 45) | Satisfactory | Action Level: not more than 352,000 particles of 0.5 µm size and larger per cubic meter of air for any buffer area. |
| 46) | Satisfactory | Particulate count of ISO 8 ante performed every 6 months or more frequently. |
| | **Comments:** six months | |
| 47) | Satisfactory | Action Level: not more than 3,520,000 particles or 0.5 µm size and larger per cubic meter of air for any ante-area. |
| **Environment Monitoring (Viable)** | | |
| 48) | Satisfactory | Does pharmacy have an environmental sampling plan? |
| 49) | Satisfactory | Surface Testing of ISO 5 PEC (LAFW,BSC,CAI,CACI) performed every 6 months or more frequently. Note Frequency and Type of Media used (Best practice Bacterial & Fungal growth supported media). |
| 50) | Satisfactory | Action level for ISO 5 PEC Surface Testing: >3 CFUs. |
| 51) | Satisfactory | Surface Testing of ISO 7 Buffer Room with TSA performed every 6 months or more frequently. Note Frequency and Type of Media used (Best practice Bacterial & Fungal growth supported media. |
| 52) | Satisfactory | Action Level for ISO 7 Buffer Surface Testing: >5CFUs. |
| 53) | Satisfactory | Surface Testing of ISO 8 Ante Room with TSA performed every 6 months or more frequently. Note Frequency and Type of Media used (Best practice Bacterial & Fungal growth supported media). |
| 54) | Satisfactory | Action Level for ISO 8 Ante room Surface Testing >100 CFUs. |
| 55) | Satisfactory | Air Impact Sampling of ISO 5 PEC (LAFW, BSC, CAI, CACI) with TSA performed every 6 months or more frequently. Note Frequency. |

| Sterile | | |
|---|---|---|
| | **Answer** | **Question** |
| 56) | Satisfactory | Air Impact Sampling of ISO 5 PEC (LAFW, BSC, CAI, CACI) with Fungal Specific Media performed every 6 months or more frequently. Note Frequency (Required for High Risk Only, best practice for Medium & Low Risk). |
| 57) | Satisfactory | Action Level for ISO 5 PEC Air Sampling:>1 CFU. |
| 58) | Satisfactory | Air Impact Sampling of ISO 7 Buffer Room with TSA performed every 6 months or more frequently. Note Frequency. |
| 59) | Satisfactory | Air Impact Sampling of ISO 7 Buffer Room with Fungal Specific Media performed every 6 months or more frequently. Note Frequency (Required High Risk Only, Best Practice for Medium and Low Risk). |
| 60) | Satisfactory | Action Level for ISO 7 Buffer Air Sampling:>10 CFUs. |
| 61) | Satisfactory | Air Impact Sampling of ISO 8 Ante Room with TSA performed every 6 months or more frequently. Note Frequency. |
| 62) | Satisfactory | Air Impact Sampling of ISO 8 Ante Room with Fungal Specific Media performed every 6 months or more frequently. Note Frequency (Required for High Risk Only, Best Practice for Medium & Low Risk). |
| 63) | Satisfactory | Acton Level for ISO 8 Ante Room Air Sampling: >100 CFUs. |
| 64) | Satisfactory | Volume of Air collected is 400-1000 liters. |
| **Compounding Record** | | |
| 65) | Satisfactory | Official or assigned name, strength, and dosage form of the preparation |
| 66) | Satisfactory | Master Formulation Record reference for the preparation. |
| 67) | Satisfactory | Names and quantities of all components |
| 68) | Satisfactory | Sources, lot numbers, and expiration dates of components. |
| 69) | Satisfactory | Total quantity compounded |
| 70) | Satisfactory | Name of the person who prepared the preparation, name of the person performed the quality control procedures, and name of the compounder who approved the preparation. |
| 71) | Satisfactory | Date of preparation; |
| 72) | Satisfactory | Assigned control or prescription number |
| 73) | Satisfactory | Assigned BUD |
| 74) | Satisfactory | Duplicate label as described in the Master Formulation Record |
| 75) | Satisfactory | Description of the final preparation. |
| 76) | Satisfactory | Documentation of any quality control issues and any adverse reactions or preparation problems reported by patient or caregiver. |
| 77) | Satisfactory | For Terminally Sterilized preparations: Filter integrity (bubble point) test results, along with lot number and expiration date of the filter, or biological indicator testing for steam sterilization (autoclave), or bacterial endotoxin testing of ECVs for dry heat sterilization. |
| **Master Formulation Records** | | |
| 78) | Satisfactory | Official or assigned name, strength, and dosage form of the preparation |
| 79) | Satisfactory | Calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients (API). |
| 80) | Satisfactory | Description of all ingredients and their quantities. |
| 81) | Satisfactory | Compatibility and stability information, including references when available. |
| 82) | Satisfactory | Equipment needed to prepare the preparation, when appropriate. |
| 83) | Satisfactory | Mixing instructions that should include: a. order of mixing b. mixing temperatures or other environmental controls c. duration of mixing d. other factors pertinent to the replication of the preparation as compounded |
| 84) | Satisfactory | Sampling labeling information, which shall contain, in addition to legally required information: a. generic name and quantity or concentration of each active ingredient b. assigned BUD c. storage conditions d. prescription or control number, whichever is applicable |
| 85) | Satisfactory | Container used in dispensing. |
| 86) | Satisfactory | Packaging and storage requirements. |

| Sterile | | |
|---|---|---|
| | **Answer** | **Question** |
| 87) | Satisfactory | Description of final preparation. |
| 88) | Satisfactory | Quality control procedures and expected results. |
| **Sterile BUD (Absence of Sterility Testing)** | | |
| 89) | Satisfactory | Low Risk: 48 hrs Room Temperature; 14 days Refrigerated & 45 days Frozen. |
| 90) | Satisfactory | Medium Risk: 30 hrs Room Temperature; 9 days Refrigerated & 45 days Frozen. |
| 91) | Satisfactory | High Risk: 24 hrs Room Temperature; 3 days Refrigerated & 45 days Frozen. |
| **Extended Sterile BUD (USP <71>)** | | |
| 92) | Satisfactory | Any Literature Used documented. |
| 93) | Not Applicable | Potency over time testing. |
| 94) | Satisfactory | Stability indicating assay. |
| 95) | Satisfactory | Method suitability performed per compound documented. |
| 96) | Satisfactory | Membrane filtration testing (preferred over direct inoculation). |
| 97) | Satisfactory | Equivalent testing to membrane testing. |
| **Items to be Tested (USP <71>)** | | |
| 98) | Not Applicable | Parenteral Preparations - Zero - 100 containers - 4 or 10% whichever is greater. 101 - 500 containers - 10. 501 or more containers - 20 or 2% whichever is less Large Volume - 10 or 2% whichever is less (give examples of each). |
| 99) | Not Applicable | Antibiotic Solids - Pharmacy bulk packages <5g - 20 pharmacy bulk packages >5g - 6 . Bulks and Blends - See Bulk Solid Products |
| 100) | Satisfactory | Ophthalmics or other non-injectable preparations - If product is in single dose containers - same as parenteral; otherwise <200 containers - 2 or 5% whichever is greater >200 containers - 10 |
| 101) | Not Applicable | Bulk Solid Products - Zero - 4 containers - Each container 5 - 50 containers - 4 or 20% whichever is greater 51 or more containers - 10 or 2% whichever is greater. |
| **Bacterial Endotoxin Testing** | | |
| 102) | Satisfactory | All High Risk Level CSPs in batches of >25 identical individual single dose packages . |
| 103) | Satisfactory | All High Risk Level CSPs in Multiple Dose Vials (MDVs) for administration to multiple patients. |
| 104) | Satisfactory | All High Risk Level CSPs that are exposed longer than 12 hours at 2 - 8 degrees C OR exposed longer than 6 hours above 8 degrees C. |
| **Personnel Training: Didactic/Observation/Writing** | | |
| 105) | Satisfactory | People who fail testing are retrained, reevaluated, and pass testing prior to resuming compounding. |
| 106) | Satisfactory | Aseptic Technique (should include observational checklist). |
| 107) | Satisfactory | Must pass media fill prior to initiation of compounding then 1 every 12 months for Low & Medium Risk and every 6 months for high risk. All media fills should mimic most complex manipulations of pharmacy regardless of risk level & should be performed when staff is at their worst. |
| 108) | Satisfactory | Hand cleansing (should include observational checklist). |
| 109) | Satisfactory | Inspection and final release of preparations . |
| 110) | Satisfactory | Fingertip test documentation for Glove Finger- tip Testing x 3 initially with Zero CFUs, during process GFT, 1 every 12 months for Low & Medium Risk and every 6 months for high risk with <3 CFUs; documentation must include lot, exp., & staff involved. |
| 111) | Satisfactory | Cleaning and disinfecting of compounding surfaces & facility on daily and monthly basis (should include observational checklist). |
| 112) | Satisfactory | NIOSH regulated compounding - Don appropriate PPEs gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, double glove with sterile chemo-type gloves. |
| 113) | Satisfactory | Protect personnel and environment from powders and cross contamination by using powder containment. |
| 114) | Satisfactory | Identify, weigh and measure ingredients. |
| 115) | Satisfactory | Training in sterilization and depyrogenation techniques such as: autoclaving, sterile filtration, dry heat sterilization and dry heat depyrogenation, etc. |
| **Personnel Training: Gown & Garb** | | |

| Sterile | | |
|---|---|---|
| | **Answer** | **Question** |
| 116) | Satisfactory | Gowning, Garbing, and Gloving should include observational checklist & personnel file. |
| 117) | Satisfactory | Staff removes all outer garments (coats, hats, jackets, scarves, sweaters, and vests). |
| 118) | Satisfactory | Staff removes all cosmetics and all visible jewelry or piercings. |
| 119) | Satisfactory | Staff dons shoe covers, head covers, beard covers (if applicable), and face masks. |
| 120) | Satisfactory | Hand cleansing is performed by cleaning debris under finger nails using a disposable nail pick, and vigorous hand washing to forearms for at least 30 seconds. Use of lint free disposable towels. |
| 121) | Satisfactory | Staff dons gowns that are non-shedding with sleeves that fit snuggly around the wrist and encloses neck. Note: Gowns can be reused for on shift only. Hair covers, shoe covers, beard covers, face mask, and gloves can only be used one time. |
| 122) | Satisfactory | Once inside the buffer, antiseptic hand cleansing is performed using a waterless alcohol based surgical scrub with persistent activity. |
| 123) | Satisfactory | Staff dons sterile powder free gloves. |
| 124) | Not Applicable | For CAI and CACI sterile gloves must be donned over the gauntlet gloves. |

NORTH CAROLINA BOARD OF PHARMACY

Facility: Brava NC
Address: 3800 Gateway Centre Blvd Ste 308A
Morrisville, NC 27560
Permit Type: Pharmacy
Permit #: 14867
Re-Issue Date: 11/04/2022
Expiration Date: 12/31/2023
Pharmacy Manager: Natalie Walters Young (#26004)

NC Law requires notification of address change within 30 days.

PLEASE NOTIFY BOARD OF NAME AND/OR ADDRESS CHANGE

REFER TO YOUR LICENSE NUMBER IN ANY COMMUNICATION

Permit #: 14867

# NORTH CAROLINA BOARD OF PHARMACY

# 2023 Pharmacy

This is to certify that

**Brava NC LLC**

doing business as

**Brava NC**

3800 Gateway Centre Blvd Ste 308A Morrisville, NC 27560 Wake

Has been renewed for the year ending December 31st 2023, as required by law and is issued to the pharmacist-manager pursuant to the representations made in application therefore. The issuance of this renewal permit is not complete and the permit is not valid until countersigned in the space indicated below by the pharmacist-manager as represented in the application. THIS PERMIT CERTIFICATE MUST BE CONSPICUOUSLY DISPLAYED IN THE PHARMACY TO WHICH IT APPLIES. Pharmacy permits are not transferable and may be revoked for the causes specified in the Law and the Rules and Regulations of the Board.

Natalie Walters Young (#26004)

11/04/2022
Re-Issued

PRESIDENT

EXECUTIVE DIRECTOR

NC Board of Pharmacy, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| FR1257826 | 07-31-2025 | $888 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N,3, 3N,4,5 | RETAIL PHARMACY | 03-13-2022 |

BRAVA NC
3800 GATEWAY CENTRE BLVD STE 308A
MORRISVILLE, NC 275606220

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

**THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.**

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3800 GATEWAY CENTRE BLVD STE 308A
MORRISVILLE, NC 275606220

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Form DEA-223 (9/2016)

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206 – Reno, NV 89521 – (775) 850-1440

Send to State Board of Pharmacy for completion: A separate letter is acceptable. Do not return with application unless it has been completed by the licensing agency.

## LICENSE VERIFICATION

Name: Brava NC LLC

Address: 3800 Gateway Centre Blvd., Suite 308-A

City: Morrisville State: NC Zip: 27560

I hereby authorize the North Carolina Board of Pharmacy to furnish to the Nevada State Board of Pharmacy, the information requested below.

Signature of Applicant Ann Randall

THIS FORM MUST BE FORWARDED TO THE HOME STATE LICENSING AGENCY FOR COMPLETION. DO **NOT** WRITE BELOW THIS LINE

| License Number | License Status | Date License Issued | Date License Expires |
|---|---|---|---|
| 148167 | active | 1/24/22 | 12/31/23 |

| Has this license been encumbered in any way? | Type of Encumbrance: (if any) |
|---|---|
| ☐ Yes ☑ No | ☐ Revoked ☐ Surrendered ☐ Limited<br>☐ Suspended ☐ Restricted ☐ Probation<br>Please attach copies of any pertinent legal documents |

USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS IF NECESSARY

| | |
|---|---|
| Has the applicant been convicted of any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? (If yes, please explain) | ☐ Yes ☑ No |
| Has the applicant furnished any false or fraudulent material in any applications made in connection with drug manufacturing or distribution? (if yes, please explain) | ☐ Yes ☑ No |
| Have any inspections of the applicant resulted in deficient ratings? (If yes, please explain) | ☐ Yes ☑ No |
| Has applicant met all licensing requirements of your state? (If no, please explain) | ☑ Yes ☐ No |

| Signature of State Official | Title | State | Date | State Seal |
|---|---|---|---|---|
| Leslie Wilson | admin | NC | 3/23/23 | |

# 8B

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Pharmacy Application

**Non-Refundable $500.00 Fee**

Rev (8/02/2022)

| Facility Location | Application Type (check all applicable) | Pharmacy Type (check all applicable) | Services the Pharmacy will Provide (check all applicable) |
|---|---|---|---|
| ☐ Nevada<br>☒ Out-of-State | ☒ New Pharmacy<br>☐ Ownership Change*<br>☐ Location Change *<br>☐ Name Change*<br><br>* If making a change, provide license #:<br><br>PH_____ | ☒ Retail/Community<br>☐ Hospital (# beds _____)<br>☐ Internet<br>☐ Nuclear<br>☐ Other: | ☒ Retail/Community<br>☒ Non-sterile Compounding<br>☒ Sterile Compounding<br>☒ Mail-Order Service<br>☐ Off-site Cognitive Services<br>☐ Long Term Care<br>☐ Hospital<br>☐ Other: |

| Days of Operation | | Ownership Type (check applicable box) |
|---|---|---|
| ☒ Monday | ☒ Friday | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12) |
| ☒ Tuesday | ☐ Saturday | ☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12) |
| ☒ Wednesday | ☐ Sunday | ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12) |
| ☒ Thursday | ☐ Holidays | ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12) |

### Section 1: General Information

Pharmacy Name: Primera Compounding, LLC DBA Primera Professional Pharmacy

Physical Address: 3745 Highway 6

City: Sugar Land State: TX Zip: 77478

Mailing Address (if different from physical address): n/a

City: _____ State: _____ Zip: _____

Telephone: 832-562-3993 Toll Free # (NAC 639.708, NRS 639.23286): 800-610-2521

Fax: 346-321-4500 Contact Email: admin@primerarx.com

Website: www.primerarx.com

Nevada Business License # (if applicable) n/a

Supervising/Managing Pharmacist Name (NRS 639.220): Paula Hooper

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23526

**Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)**

| | |
|---|---|
| Name: n/a | NV Pharmacist Registration #: n/a |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |

| **Section 3: History of Company** | **Yes** | **No** |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✓ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction? | | ✓ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry? | | ✓ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✓ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✓ |

**If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.**

**Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)**

| | | |
|---|---|---|
| Name: n/a | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

**Section 5: Publicly Traded Corporation**

State of Incorporation: n/a

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 6: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: Texas/Secretary of State

Parent Company (if any): _____

Corporation/Organization Name: Primera Compounding, LLC

Mailing Address: 30444 Southwest Fwy

City: Rosenberg State: TX Zip: 77471

Telephone: 832-562-3993 Email: admin@primerarx.com

Contact Person Name: Patty Heinz

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

**Section 7: Partnership**

Partnership Name: n/a

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 8: Sole Owner**

Owner's Name: n/a

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

**Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)**

**Statement of Responsibility**

1. I am the VP Operations (title) for Primera Compounding, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Patty Heinz

Print Name of Authorized Person



Original signature of Authorized Person (copies or stamps not accepted)

10/19/2022

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Patty Heinz

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

10/19/2022

Date

| Board Use Only | Date Received: 11-2-22 | Amount: 500.00 CK-697064 |
|---|---|---|

| Section 12: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a) | ✓ | ✓ | | |

Basil Raad; Officer

| | | | | |
|---|---|---|---|---|
| • List the top four stockholders and their percent ownership. NRS 639.231(3) | ✓ | ✓ | | |

OCuSOFT, Inc; 100%

| | | | | |
|---|---|---|---|---|
| • List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b) | | ✓ | | |

OCuSOFT, Inc; 100%

| | | | | |
|---|---|---|---|---|
| • **Personal History Record Application** http://bop.nv.gov/Services/newapps/Business/ must be completed by:<br>a. **For Non-publicly traded -** The top 4 shareholder/stockholders.<br>b. **For Partnerships -** All general partners; all limited partners who hold 10% or more of the interest.<br>c. **For Sole Owner** - The owner. | | ✓ | ✓ | ✓ |

We were informed that we are exempt from providing a Personal History Record Application, since the pharmacy is owned by a corporation.

| | | | | |
|---|---|---|---|---|
| • **Internet Pharmacy Services Certification (REQUIRED FOR PHARMACIES PROVIDING INTERNET PHARMACY SERVICES)** | ✓ | ✓ | ✓ | ✓ |

n/a

# Nevada State Board Of Pharmacy

(Licensee mailing address for window envelope)

THIS STUB IS YOUR RECEIPT

Date: 04/04/2023
Amount:
License #: 23526

Paula R. Hooper

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Pharmacist
Effective Date:04/04/2023
Expires:10/31/2023

Paula R. Hooper

License #
23526
Active

IDENTIFICATION ONLY
DOES NOT MEET POSTING REQUIREMENTS

Trim ID Card to fit your wallet

Cut Here

NEVADA
STATE BOARD OF PHARMACY
Pharmacist

License Type: Pharmacist
License #: 23526
Effective Date:04/04/2023

Expires: 10/31/2023
STATUS: Active

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENSED

Paula R. Hooper

**NONTRANSFERABLE**

POST THIS LICENSE PROMINENTLY IN A CONSPICUOUS PLACE

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206 – Reno, NV 89521 – (775) 850-1440

Send to State Board of Pharmacy for completion: A separate letter is acceptable. Do not return with application unless it has been completed by the licensing agency.

## LICENSE VERIFICATION

Name: Primera Professional Pharmacy

Address: 3745 Highway 6

City: Sugar Land State: TX Zip: 77478

I hereby authorize the Texas State Board of Pharmacy to furnish to the Nevada State Board of Pharmacy, the information requested below.

Signature of Applicant [signature]

THIS FORM MUST BE FORWARDED TO THE HOME STATE LICENSING AGENCY FOR COMPLETION. DO **NOT** WRITE BELOW THIS LINE

| License Number | License Status | Date License Issued | Date License Expires |
|---|---|---|---|
| 34197 | Active | March 17, 2022 | March 31, 2024 |

| Has this license been encumbered in any way? | Type of Encumbrance: (if any) |
|---|---|
| ☐ Yes ☒ No (see attached) | ☐ Revoked ☐ Surrendered ☐ Limited ☐ Suspended ☐ Restricted ☐ Probation Please attach copies of any pertinent legal documents |

USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS IF NECESSARY

| | |
|---|---|
| Has the applicant been convicted of any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? (If yes, please explain) | ☐ Yes ☒ No |
| Has the applicant furnished any false or fraudulent material in any applications made in connection with drug manufacturing or distribution? (if yes, please explain) | ☐ Yes ☒ No |
| Have any inspections of the applicant resulted in deficient ratings? (If yes, please explain) | ☐ Yes ☒ No |
| Has applicant met all licensing requirements of your state? (If no, please explain) | ☒ Yes ☐ No |

| Signature of State Official | Title | State | Date | Sta |
|---|---|---|---|---|
| Lauren D. Briggs | Assistant General Counsel | Texas | October 27, 2022 | |

TEXAS BOARD OF PHARMACY

# TEXAS STATE BOARD OF PHARMACY

| | |
|---|---|
| **Re:** | Primera Professional Pharmacy |
| **Address:** | 3745 Highway 6<br>Sugar Land, Texas 77478 |
| **License No.:** | 34197 |
| **Date Issued:** | March 17, 2022 |
| **Licensure Status:** | Active |
| **Expiration Date:** | March 31, 2024 |
| **Type of Pharmacy:** | Community Sterile Compounding |
| **Prior Disciplinary Orders:** | No |

The Texas State Board of Pharmacy maintains records regarding licensure and disciplinary action against a licensee. Primera Professional Pharmacy (Texas Pharmacy License #34197) has not been subject to disciplinary action by the Texas State Board of Pharmacy.

Form Completed by:

Eamon D. Briggs
Assistant General Counsel
Texas State Board of Pharmacy

October 27, 2022
Date

The Texas Department of State Health Services, Drugs and Medical Devices Division, Wholesaler Registration, 1100 W. 49th Street, Austin, TX 78756, is responsible for issuing registrations to wholesale drug distributors and drug manufacturers in Texas.

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

John B. Scott
Secretary of State

# Office of the Secretary of State

## Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate of Formation for Primera Compounding, LLC (file number 803544712), a Domestic Limited Liability Company (LLC), was filed in this office on February 11, 2020.

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on October 19, 2022.

John B. Scott
Secretary of State

2134



This certifies that the pharmacy named below is hereby licensed to operate as a Class **AS** pharmacy.

License No. **34197** Expiration Date: **3/31/2024**

Balances: **2**

**PRIMERA PROFESSIONAL PHARMACY**
**3745 HWY 6**
**SUGAR LAND TX 77478**

**Allison Vordenbaumen Benz, R.Ph., M.S.**
**Executive Director/Secretary**

**MUST BE DISPLAYED IN FULL PUBLIC VIEW**

PRIMERA PROFESSIONAL PHARMACY
3745 HIGHWAY 6
SUGAR LAND, TX 77478-0000

10004164 2/001626-171-0

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| FP1295989 | 03-31-2025 | $888 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N, 3,3N,4,5 | RETAIL PHARMACY | 03-24-2022 |

*PRIMERA PROFESSIONAL PHARMACY*
*3745 HIGHWAY 6*
*SUGAR LAND, TX 77478-0000*

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

**THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.**

**CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE**
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| FP1295989 | 03-31-2025 | $888 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N, 3,3N,4,5 | RETAIL PHARMACY | 03-24-2022 |

PRIMERA PROFESSIONAL PHARMACY
3745 HIGHWAY 6
SUGAR LAND, TX 77478-0000

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THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-500
Austin, TX 78701
512-305-8000

# Notice of Inspection

## Facility Information

Name: *PRIMERA PROFESSIONAL PHARMACY* License Number: *34197*

Address: *3745 HWY 6, SUGAR LAND, TX 77478* Phone: *(832) 562-3993*

Email: *Info@primerarx.com*

Class of License: *AS* License Expiration: *03/31/2024*

DEA #: *FP1295989* DEA Expiration: *03/31/2025*

## Inspection Information

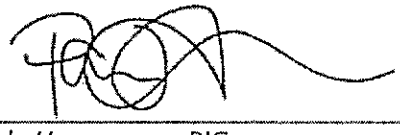
Type: *Compliance* Purpose: *New Pharmacy*

Date: *09/16/2022* Arrival Time: *2:15 PM*

## Acknowledgment

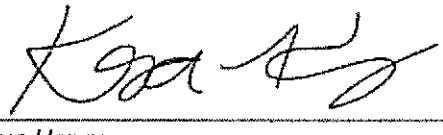
This is to acknowledge that Texas State Board of Pharmacy Agent has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

1. I have read the Notice of Inspection and understand its contents and purpose;
2. I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
3. I have had the purpose of the entry into the above-described facility by the Boards agent stated to me; and
4. I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.



*Paula Hooper* *PIC* *45469*

## Witness



*Keya Henry*

Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-500
Austin, TX 78701
512-305-8000

# Inspection Report

## Facility Information

Name: *PRIMERA PROFESSIONAL PHARMACY* License Number: *34197*

Class of License: *AS*

## Inspection Information

Type: *Compliance* Purpose: *New Pharmacy*

Date: *09/16/2022* Arrival Time: *2:15 PM* Departure Time: *5:45 PM*

Action Taken: *Inspection*

General Comments: *Pharmacy holds active out of state pharmacy license in AZ, IL, IN, PA, UT.*

## Licenses/Registration

| | |
|---|---|
| Verify personnel have active licenses & address with PIC/RPh if necessary | *Satisfactory* |
| 01. Required licenses posted | *Satisfactory* |
| 09. Active licenses/certifications | *Satisfactory* |
| 62. No aiding and abetting | *Satisfactory* |
| 65. Proper registration procedures | *Satisfactory* |
| 79. Identification badges | *Satisfactory* |

## Inventory Records

| | |
|---|---|
| 15. Change of PIC inventory | *Satisfactory* |

Comment

*Change of PIC inventory completed on: 03/25/22 COB*

| | |
|---|---|
| 17. Meets inventory requirements | *Satisfactory* |
| 59. Proper drug destruction | *Satisfactory* |
| 68. Change of ownership controlled substance inventory | *Not Applicable* |
| 69. Annual controlled substance inventory | *Satisfactory* |

Comment

*Initial controlled substance inventory completed on: 03/29/2022*

Comment

*Annual controlled substance inventory completed on: 06/06/22 OOB*

| | |
|---|---|
| 69. Annual controlled substance inventory *(continued)* | *Satisfactory* |

## Notifications

| | |
|---|---|
| 31. Closed pharmacy (Is pharmacy engaged in the business described in application for licensure?) | *Satisfactory* |
| 34. Notifications | *Satisfactory* |
| 76. PIC (Does the pharmacy have a pharmacist-in-charge?) | *Satisfactory* |

## Environment/Equipment/Security

| | |
|---|---|
| 03. Orderly/Clean | *Satisfactory* |
| 04. Balance inspection | *Satisfactory* |

**Comment**

*2 Balances on-site*

| | |
|---|---|
| 05. Equipment Inspection | *Satisfactory* |
| 07. Security | *Satisfactory* |
| 08. Environment | *Satisfactory* |
| 48. Drugs (procurement, temperature, security, out-of-date, samples) | *Satisfactory* |
| 90. TSBP complaint notification | *Satisfactory* |

## Controlled Substances

| | |
|---|---|
| 10. Prescriptions separated | *Satisfactory* |
| 24. Theft/Loss | *Satisfactory* |

**Comment**

*No theft or loss has occurred.*

| | |
|---|---|
| 26. Controlled substance prescription compliance | *Satisfactory* |
| 30. Controlled substance invoices dated/initialed by pharmacist | *Satisfactory* |
| 35. Controlled substance invoices separated | *Satisfactory* |
| 46. Drug distribution | *Satisfactory* |
| 53. Possession of controlled substances | *Satisfactory* |
| 57. Corresponding responsibility (Does the pharmacist exercise sound professional judgment with respect to the accuracy or authenticity of a prescription drug order?) | *Satisfactory* |

## Labeling/Prepackaging

| | |
|---|---|
| 32. Prescription label (Is prescription label complete?) | *Satisfactory* |

| | |
|---|---|
| 45. Proper dispensing/labeling | *Satisfactory* |
| 54. Proper prepackaging procedures | *Satisfactory* |

## Library

| | |
|---|---|
| 06. Required Library | *Satisfactory* |

## Training

| | |
|---|---|
| 60. Documentation of required training | *Satisfactory* |
| 61. Supervision of supportive personnel | *Not Applicable* |

## Patient/Computer/Dispensing Records

| | |
|---|---|
| 18. Records available | *Satisfactory* |
| 21. Data processing records complete | *Satisfactory* |
| 22. Data processing system compliance | *Satisfactory* |
| 25. Prescriptions (complete, retrievable, auto-refills, accelerated refills) | *Satisfactory* |
| 37. Legal dispensing (Are valid prescriptions being dispensed by a pharmacist?) | *Satisfactory* |
| 56. Prescription transfers | *Not Inspected* |
| 67. Written drug information provided | *Satisfactory* |
| 80. Patient counseling | *Satisfactory* |
| 82. Patient Medication Records | *Satisfactory* |
| 84. Drug regimen review | *Satisfactory* |
| 86. Absence of pharmacist records | *Satisfactory* |

## Policies & Procedures

| | |
|---|---|
| 70. Required policies & procedures | *Satisfactory* |
| 92. Automated dispensing policy & procedures | *Not Applicable* |

## Non-Sterile Compounding

| | |
|---|---|
| 38. Area for non-sterile compounding | *Satisfactory* |
| 43. Records for non-sterile compounding | *Satisfactory* |

## Compounded Dosage Forms

| | |
|---|---|
| Allergen extracts | *No* |
| Parenteral solutions | *No* |

| | |
|---|---|
| Parenteral suspensions | *No* |
| Preservative-free parenterals | *No* |
| Ophthalmic preparations | *Yes* |
| Oral or nasal inhalation preparations (not topical spray) | *No* |
| Bath or soaks for live organs/tissues | *No* |
| Irrigations for wounds or body cavities | *No* |
| Any other sterile preparations (implants, pellets, etc) [list] | *No* |
| Investigational drugs | *No* |
| Blood products or other biological materials (wound care, autologous, eye drops, etc) | *No* |
| Any compounds using federally controlled substances Schedule I-V (list and percentage) | *No* |
| Does the pharmacy use lyophilizer? | *No* |

## Environment (Sterile)

| | |
|---|---|
| S109. Is the cleanroom clean and free of objects that shed particles? | *Satisfactory* |
| S110. Is the cleanroom used only for sterile preparations? | *Satisfactory* |
| S119. Does the cleanroom contain only appropriate supplies? | *Satisfactory* |
| S101. Does the ante-area provide at least ISO Class 8 air quality under dynamic conditions? | *Satisfactory* |
| S115. Does the ante-area contain a hands-free sink with hot and cold running water? | *Satisfactory* |
| S102. Does the buffer area provide at least ISO Class 7 air quality under dynamic conditions? | *Satisfactory* |
| S106. Is the buffer area free from sources of water (e.g., sink, floor drains)? | *Satisfactory* |
| S108. Is there hands-free access to the buffer area? | *Satisfactory* |
| S113. Are floors, walls, ceilings & fixtures smooth, impervious and free from cracks & crevices? | *Satisfactory* |
| S112. Does the floor covering enable regular disinfection? | *Satisfactory* |
| S118. Are supplies stored above the floor to permit adequate floor cleaning? | *Satisfactory* |
| S127. Does the clean room have a pressure gauge or velocity meter to monitor pressure differential between buffer area and ante-area and between the ante-area and the general environment? Is the pressure differential at least 0.02" wc? | *Satisfactory* |
| S116. Are temperature and humidity monitored, documented and within the required range? | *Satisfactory* |

291.133(d)(6)(A)(ii).

Environment. Compounding facilities shall be physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites. Low and Medium Risk Preparations. A pharmacy that prepares low- and medium-risk preparations shall have a clean room for the compounding of sterile preparations that is constructed to minimize the opportunities for particulate and microbial contamination. The clean room shall:

be maintained at a temperature of 20 degrees Celsius or cooler and at a humidity below 60%

S116. Are temperature and humidity monitored, documented and within the required range? *(continued)* — *Satisfactory*

Comment

*Advised to maintain temperature at 60 degrees F or cooler and and humidity below 60%.*

S167. Is there a thermometer available for the cleanroom and refrigerator(s)? — *Satisfactory*

## Primary Engineering Control (PECs) Device

S126. Is the laminar air flow hood located in a buffer area that has a minimum differential positive pressure of 0.02" wc? — *Satisfactory*

S121. Is the PEC able to maintain at least ISO Class 5 conditions while compounding sterile preparations? — *Satisfactory*

S246. Are hazardous drugs prepared in a Class II/III vertical flow BSC or CACI located in an ISO Class 7 area physically separated from other areas? — *Satisfactory*

S247. Does the area where the BSC or CACI is located have not less than 0.01" wc negative pressure adjacent to the positive pressure ISO Class 7 area? — *Satisfactory*

S105. Does the CAI or CACI provide unidirectional airflow? — *Not Applicable*

S104. If the CAI or CACI is used for high-risk sterile compounding, is it placed in an ISO Class 8 area? — *Not Applicable*

S122. If the CAI is not required to be placed in an ISO Class 7 area, does the pharmacy maintain documentation from the manufacturer? — *Not Applicable*

S124. Is the PEC certified by an independent contractor every 6 months and when relocated? — *Satisfactory*

S125. Are prefilters inspected periodically and replaced as needed? — *Satisfactory*

S128. Are differential pressures monitored and documented at least every work shift (at a minimum daily) or by a continuous recording device? — *Satisfactory*

## Equipment and Supplies

S174. Does the pharmacy have disposable needles, syringes, and other required or applicable supplies? — *Satisfactory*

S177. Does the pharmacy have lint-free towels or wipes? — *Satisfactory*

S180. Does the pharmacy have masks, caps, gowns with tight cuffs, shoes covers, and beard covers (if applicable)? — *Satisfactory*

S176. Does the pharmacy have handwashing agents with bactericidal action? — *Satisfactory*

S175. Does the pharmacy have disinfectant cleaning solutions and dedicated cleaning supplies? — *Satisfactory*

S179. Does the pharmacy have hazardous spill kits, if applicable? — *Satisfactory*

S171. Does the pharmacy have appropriate containers for needles and syringes? — *Satisfactory*

| | |
|---|---|
| S170. Does the pharmacy have sterile isopropyl alcohol, sterile gloves, and waterless alcohol-based surgical hand scrub? | *Satisfactory* |
| S178. Does the pharmacy have appropriate filters and filtration equipment? | *Satisfactory* |
| S181. If an automated compounding device is used, does the pharmacy calibrate & verify the device for accuracy, and document at least daily? | *Satisfactory* |
| S172. Does the pharmacy have packaging or delivery containers to maintain proper storage conditions for sterile preparations? | *Satisfactory* |

## High Risk CSPs

| | |
|---|---|
| S103. If high-risk CSPs are compounded, does the buffer area provide physical separation from other compounding areas? | *Satisfactory* |
| S231. Is sterility testing performed if CSPs are prepared in groups > 25, or | *Satisfactory* |
| S232. If MDVs are prepared for multiple patients or when exposed > 12 hours at 2-8 degrees C before sterilized, or | *Satisfactory* |
| S233. If exposed > 6 hours at warmer than 8 degrees C before sterilized? | *Satisfactory* |
| S237. Are all non-sterile measuring, mixing, and purifying devices rinsed thoroughly with pyrogen-free or depyrogenated sterile water, and then thoroughly drained or dried immediately before use for high-risk sterile compounding? | *Satisfactory* |
| S238. Are all high-risk sterile solutions subjected to terminal sterilization prefiltered using no larger than a 1.2-micron filter to remove particulate matter? Is sterilization by filtration performed with a sterile 0.2 – 0.22 micrometer pore size filter within an ISO Class 5 environment or better? | *Satisfactory* |
| S165. Are filter integrity tests being performed and documented (e.g., bubble point test)? | *Satisfactory* |
| S239. Are pre-sterilization procedures (weighing and mixing) completed in an ISO Class 8 environment or better? | *Satisfactory* |

## Sterile Library

| | |
|---|---|
| S154. Does the pharmacy have a reference on injectable drugs? | *Satisfactory* |
| S155. Does the pharmacy have a specialty reference? | *Satisfactory* |
| S156. Does the pharmacy have all of the required (USP chapters 71, 85, 795, 797, 1163) and applicable USP chapters? | *Satisfactory* |

## Hazardous CSPs

| | |
|---|---|
| S242. Do personnel wear protective apparel at all times when hazardous drugs are handled? | *Not Applicable* |
| S243. Do personnel use appropriate safety and containment techniques when preparing hazardous CSPs? | *Not Applicable* |
| S244. Do personnel dispose of hazardous waste in compliance with local, state, and federal regulations? | *Not Applicable* |

| | |
|---|---|
| S245. Do personnel affix a proper label, including proper precautions inside and outside of the packaging? | *Not Applicable* |
| S248. Does the pharmacy have a pressure indicator that can be readily monitored for correct room pressurization? | *Not Applicable* |
| S249. Does the pharmacy meet the requirements for low volume preparation of hazardous drugs by using a device that provides two-tiers of containment (e.g., closed-system vial transfer device within a BSC)? | *Not Applicable* |
| S250. Are hazardous drugs stored separately from other inventory in a manner to prevent contamination and personnel exposure? | *Not Applicable* |
| Does the pharmacy have a plan to comply with USP <800> by the implementation date? | *Not Applicable* |
| Are hazardous drugs stored separately in compliance with USP <800> (negative pressure at least -0.01" wc to adjacent areas and with at least 12 ACPH)? | *Not Applicable* |
| Is hazardous drug waste quarantined in a designated area? | *Not Applicable* |
| Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)? | *Not Applicable* |

## Personnel Cleansing, Garbing, Hand Hygiene

| | |
|---|---|
| S202. Does hand sanitizing and gowning occur in the ante-area (outside of the buffer area)? | *Satisfactory* |
| S180. Do compounding personnel don clean non-shedding gowns with sleeves that fit snugly around the wrists and enclose at the neck? Is the order of garbing appropriate (dirtiest to cleanest)? | *Satisfactory* |
| S194. Before entering the buffer area, do compounding personnel remove cosmetics? | *Satisfactory* |
| S195. Before entering the buffer area, do compounding personnel remove all hand, wrist, and other body jewelry/piercings? | *Satisfactory* |
| S196. Are natural nails kept neat and trim and no wearing of artificial nails or extenders? | *Satisfactory* |
| S200. Do compounding personnel remove debris from underneath fingernails using a nail cleaner under running warm water? | *Satisfactory* |
| S192. Are personnel with an apparent illness or open lesions compounding sterile preparations? | *Satisfactory* |
| S241. When compounding personnel temporarily exit the ISO Class 7 environment, are re-donning procedures properly followed? | *Satisfactory* |
| S201. Do compounding personnel engage in proper hand hygiene? | *Satisfactory* |
| S203. Do compounding personnel completely dry hands and forearms using lint-free disposable towels or hand dryer? | *Satisfactory* |
| S204. Is antiseptic hand cleansing performed using waterless alcohol-based surgical scrub once inside the buffer area and prior to donning sterile gloves? | *Satisfactory* |
| S206. Is sterile isopropyl alcohol applied to gloves throughout the day and when non-sterile surfaces are touched? | *Satisfactory* |

## Cleaning/Disinfection Procedures

| | |
|---|---|
| S182. Does the pharmacy have written procedures on the cleaning and disinfecting of the direct and contiguous compounding areas (e.g., beginning of shift, every 30 minutes, before each batch, spills)? | *Satisfactory* |
| S230. Is cleaning performed by trained personnel using approved agents (described in written SOPs)? | *Satisfactory* |
| S228. Are supplies & equipment that are removed from shipping cartons wiped with a disinfecting agent (e.g., sterile IPA)? | *Satisfactory* |
| S226. Are work surfaces and floors in the ante-area and buffer area cleaned and disinfected daily with dedicated supplies? | *Satisfactory* |
| S227. Are walls, ceilings and shelving in the ante-area and buffer area cleaned and disinfected at least monthly? | *Satisfactory* |
| S229. Does the pharmacy maintain documentation of cleaning procedures (i.e., date/time of cleaning, type of cleaning, name of individual who performed the cleaning)? | *Satisfactory* |

## Environmental Sampling

| | |
|---|---|
| S270. Is surface sampling conducted in all ISO classified areas on a periodic basis? | *Satisfactory* |
| S272. Is viable air sampling performed? | *Satisfactory* |
| S273. Is viable air sampling documented by properly trained individuals for all risk levels every 6 months? | *Satisfactory* |
| S271. Are environmental sampling results evaluated and addressed (i.e., action levels followed)? | *Satisfactory* |

## Records of CSPs

| | |
|---|---|
| S252. Does the pharmacy maintain records relating to CSPs for a minimum of 2 years? | *Satisfactory* |
| S253. Do compounding records include the date and time of preparation of a CSP? | *Satisfactory* |
| S254. Do compounding records include the complete formula of a CSP? | *Satisfactory* |
| S257. Do compounding records include the quantities of materials used in a CSP? | *Satisfactory* |
| S255. Do compounding records include the signature or initials of who prepared a CSP? | *Satisfactory* |
| S256. Do compounding records include the signature or initials of who conducted the final check of a CSP? | *Satisfactory* |
| S258. Do compounding records include the container used and the number of units prepared for a CSP? | *Satisfactory* |
| S259. Do compounding records include the criteria used to determine the beyond-use date of a CSP? | *Satisfactory* |
| S260. Do compounding records include the documentation of performance of quality control procedures? | *Satisfactory* |

| | |
|---|---|
| S261. Are master worksheets and preparation worksheets for batch compounding complete? | *Satisfactory* |
| S262. Are master worksheets developed and approved by a pharmacist? | *Satisfactory* |

## General Operational Requirements

| | |
|---|---|
| S166. Is a pharmacist available at all times (24/7)? | *Satisfactory* |
| S187. Are written SOPs developed and implemented for all significant procedures in the compounding area to include at a minimum: the facility, equipment, personnel, preparation evaluation, quality assurance, preparation recall, packaging, and storage of CSPs? | *Satisfactory* |
| S188. Does the pharmacy have all required written policies (e.g., pharmaceutical care services, sampling plan, recalls)? | *Satisfactory* |
| S158. If the pharmacy compounds commercially available products, does the pharmacy document the need by verifying and monitoring a drug shortage list (including if the preparation is quarantined/not available once removed from the shortage list)? Or, | *Satisfactory* |
| S158. Does the pharmacy document the need for compounding commercially available products by individual patient needs determined by the prescribing practitioner (i.e, hypersensitivity to inactive ingredients or alternate dosage form)? | *Satisfactory* |
| S275. If the pharmacy dispenses prescriptions to patients in other states, does the pharmacy have proper licensure in those states? | *Satisfactory* |

## Office Use Compounding & Distribution of CSPs

| | |
|---|---|
| S163. Does the pharmacy have a written agreement with the prescriber that meets all requirements to distribute compounded sterile preparations to practitioners for office use? | *Not Applicable* |
| S162. If the pharmacy is distributing CSPs to another pharmacy, does the pharmacy meet the requirements for such distribution? | *Not Applicable* |
| Is the pharmacy registered with the FDA as an Outsourcing Facility (503B)? | *Not Applicable* |

## Quality Control & Verification of Compounding Accuracy

| | |
|---|---|
| S207. Does a pharmacist review all compounding records for accuracy and perform the final check of a CSP? | *Satisfactory* |
| S185. Are periodic in-process checks for CSPs defined in written procedures and conducted as defined? | *Satisfactory* |
| S191. Are all drug components USP/NF grade substances manufactured in an FDA-registered facility? If USP/NF grade substances are not available, are the drug components of chemical grade in CP, AR, ACS, or Food Chemical Codex categories? | *Satisfactory* |
| S191. Is a Certificate of Analysis available for all components of the preparation if materials are not purchased through an FDA-registered facility? | *Satisfactory* |
| S191. Are any CSPs prepared by the pharmacy listed on the federal FDA list of drug products that are withdrawn or removed from the market for safety reasons? | *Satisfactory* |

## Veterinary Compounding

| | |
|---|---|
| Are APIs or other components labeled for veterinary use segregated or marked to prevent use for human compounding? | *Not Applicable* |
| Does the pharmacy meet the same standards for animal compounding as human compounding? | *Not Applicable* |
| Is the pharmacist knowledgeable or does the pharmacy have up-to-date references regarding species limits that can result in toxicity when compounding with particular drugs/excipients? | *Not Applicable* |
| Does the pharmacy document if the animal is a pet or used for food? | *Not Applicable* |
| Is the pharmacist familiar with, or does the pharmacy have the most up-to date references regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals? | *Not Applicable* |
| Does the pharmacy have a list of drugs and components that have been designated by state or federal authorities as prohibited ingredients in CSPs for food-producing animals? | *Not Applicable* |
| Is the pharmacist familiar with, or does the pharmacy have the most up-to-date reference regarding regulations for drug use in performance animals? | *Not Applicable* |

## Label

| | |
|---|---|
| S209. Is the CSP properly labeled to include the generic name(s), and | *Satisfactory* |
| S210. For outpatient prescriptions, does the label include a statement that the CSP has been compounded by the pharmacy? | *Satisfactory* |
| S211. Does the label include a beyond-use date? | *Satisfactory* |
| S213. If the CSP is compounded as a batch, does the label contain a unique lot number assigned to the batch, and | *Satisfactory* |
| S214. Quantity, and | *Satisfactory* |
| S215. Appropriate ancillary instructions, such as storage or cautionary statements, and | *Satisfactory* |
| S216. Any device-specific instructions, if appropriate? | *Satisfactory* |
| S220. Are CSPs assigned a beyond-use date based on the specified labeling for the drug, appropriate literature sources, or direct testing? | *Satisfactory* |

## Training & Competency Testing

| | |
|---|---|
| S129. Has each pharmacist completed the required education and training prior to engaging in sterile compounding? | *Satisfactory* |
| S130. Has each pharmacy technician completed the required education and training prior to engaging in sterile compounding? | *Satisfactory* |
| S142. Does the pharmacy maintain documentation to demonstrate that all compounding personnel have successfully passed initial competency evaluation/testing (e.g., media-fill testing, gloved fingertip/thumb testing)? Does the pharmacy have an on-the-job training program? | *Satisfactory* |

S144. Does the pharmacy maintain documentation of on-going training and testing for all compounding personnel (e.g., observation of aseptic technique, media-fill testing, gloved fingertip/thumb testing, continuing education)? *Satisfactory*

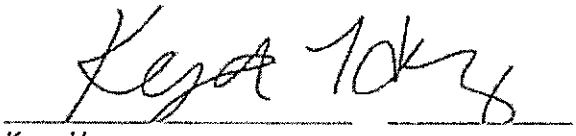
## Signatures

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted.

- Items designated as "Refer to Legal" must be rectified immediately. In addition, the matter discovered during the inspection and deemed to be a serious violation by the inspector will be referred to the Legal Division for review and possible disciplinary action; and
- Items designated as "Warning Notice" must be corrected by the deadline noted to ensure compliance with the laws and rules governing the practice of pharmacy (Note: A "Warning Notice" is issued for a minor violation, and does not equate to disciplinary action).



*Paula Hooper*



*Keya Henry*

# TEXAS STATE BOARD OF PHARMACY

Pharmacist in Charge Attestation:

I hereby attest the following statements are true and accurate (initial each statement below):

BR — I am the Pharmacist-in-Charge (PIC) of *PRIMERA PROFESSIONAL PHARMACY*, pharmacy license number , and I ☑ was/ ☐ was not present during a Compliance Inspection conducted by a Texas State Board of Pharmacy Compliance Officer/Inspector on *03/10/2022*.

BK — I received and reviewed the Notice of Inspection, Inspection Report, and Warning Notice (if applicable) issued by the Compliance Officer/Inspector.

BR — I reviewed the document titled Texas State Board of Pharmacy "Red Flags" Checklist for Pharmacies YOU MIGHT BE A PILL MILL IF (on the attestation printout).

NA — If applicable, the Warning Notice issued contains *0* deficiencies which may require corrections to resolve. I affirm that each of the deficiencies will be corrected by the date noted on the Warning Notice.

BR — I was present and completed this Attestation during the Compliance Inspection.

If not completed during the Compliance Inspection, please mail, email, or fax this completed form to the Board office within 7 days of the date of the inspection:

Texas State Board of Pharmacy
Attn: Compliance Division
333 Guadalupe St. Suite 3-500
Austin. Texas 78701
Email: inspections@pharmacy.texas.gov
Fax: 512-305-8082

Signed: B. Raad Date: *03/10/2022*

Printed Name: *Basil Raad* License No.(if applicable): *30127*

Texas State Board of Pharmacy
"Red Flags" Checklist for Pharmacies
YOU MIGHT BE A PILL MILL IF...

*Check all that apply:*

| | |
|---|---|
| | (1) Your pharmacy fills a discernable pattern of prescriptions for prescribers who write essentially the same prescriptions for numerous persons, indicating a lack of individual drug therapy |
| | (2) Your pharmacy operates with limited hours of operation or closes after a certain threshold of controlled substance prescriptions are dispensed, and has overall low prescription dispensing volume. |
| | (3) Prescriptions presented to the pharmacy are for controlled substances with popularity as street drugs, such as opiates, benzodiazepines, muscle relaxants, psychostimulants, and/or cough syrups, or any combination of these drugs. |
| | (4) The prescriptions for controlled substances contain nonspecific or no diagnoses. |
| | (5) The prescriptions are commonly for the highest strength of the drug and/or for large quantities. |
| | (6) Dangerous drugs or OTC products (such as multi-vitamins or laxatives) are added to the controlled substance prescriptions, maintaining relatively consistent 1:1 ratio of controlled substances to dangerous drugs and/or OTC products dispensed as prescriptions. |
| | (7) Prescriptions are authorized by the same prescriber with what appears to be different handwriting on the hardcopy prescription drug order forms. |
| | (8) Upon contact with the prescriber's office, you are unable to engage in comprehensive discussion with the actual prescriber, or he/she is unconcerned about your apprehensions regarding his/her prescribing practices or unwilling to provide additional information, such as treatment goals and/or prognosis with prescribed drug therapy. |
| | (9) You rely solely on the prescriber's representation, or on the representation of the individual answering the phone at the number on the prescription, that prescriptions are legitimate. |
| | (10) The prescriber's clinic is not registered as a pain management clinic by the Texas Medical Board, despite routinely receiving prescriptions from the prescriber foropiates, benzodiazepines, and/or muscle relaxants. |
| | (11) Drugs prescribed are inconsistent with the prescriber's area of practice. |
| | (12) The prescriber of the drugs is located a significant distance from your pharmacy. |
| | (13) The prescriber has been subject to disciplinary action by the licensing board, had his/her DEA registration removed, or been subject to criminal action. |
| | (14) The Texas PMP system indicates that persons are obtaining prescriptions for the same drugs from multiple prescribers or that persons are filling prescriptions for the same drugs at multiple pharmacies. |
| | (15) The person's address is a significant distance from your pharmacy and/or from the prescriber's office. |
| | (16) Multiple persons with the same address present prescriptions from the same prescriber. |
| | (17) Persons pay with cash or credit card more often than through insurance. |
| | (18) Persons presenting controlled substance prescriptions are doing so in such a manner that varies from seeking routine pharmacy services (e.g., willing to wait in long lines to receive drugs, persons arrive in the same vehicle with prescriptions from same prescriber, one person presents to pick up prescriptions for multiple others, persons refer to drugs by "street names" and/or comment on drug's color, persons seek early refills, persons travel from outside reasonable trade area of pharmacy). |
| | (19) Your pharmacy charges and persons are willing to pay more for controlled substances than they would at nearby pharmacies. |
| | (20) Your pharmacy routinely orders controlled substances from more than one drug supplier, or your pharmacy has been discontinued by a drug supplier related to controlled substance orders. |
| | (21) Sporadic and non-consistent dispensing volume (including zero dispensing) varies from day to day and week to week, and your pharmacy does not maintain operational hours each week on Monday through Friday. |
| | (22) Your pharmacy employs or contracts security personnel during operational hours to prevent problems. |
| | (23) Your pharmacy has been previously warned or disciplined by the Texas State Board of Pharmacy for inappropriate dispensing of controlled substances (i.e., corresponding responsibility). |

If you checked any of the above items, you should review the laws and rules regarding corresponding responsibility and non-therapeutic dispensing, especially Board rule §291.29, in the law book or on our website: www.pharmacy.texas.gov (click on Texas Pharmacy Rules and Laws). Additional educational material is available at: http://www.pharmacy.texas.gov/Nontherapeutic.asp. Failure of pharmacies and pharmacists to detect patterns of inappropriate dispensing of prescription drugs is unprofessional practice and constitutes grounds for disciplinary action.

Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-500
Austin, TX 78701
512-305-8000

# Notice of Inspection

## Facility Information

Name: *PRIMERA PROFESSIONAL PHARMACY*
License Number:
Address: *3745 HWY 6, SUGAR LAND, TX 77478*
Phone: *346-350-5194*
Email:
*basil.raad@primeracompounding.com*
Class of License: *AS*
License Expiration:
DEA #: *N/A*
DEA Expiration:

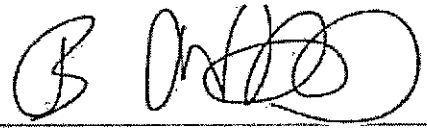
## Inspection Information

Type: *Compliance*
Purpose: *Pre-Inspection*
Date: *03/10/2022*
Arrival Time: *2:10 PM*

## Acknowledgment

This is to acknowledge that Texas State Board of Pharmacy Agent has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

1. I have read the Notice of Inspection and understand its contents and purpose;
2. I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
3. I have had the purpose of the entry into the above-described facility by the Boards agent stated to me; and
4. I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.

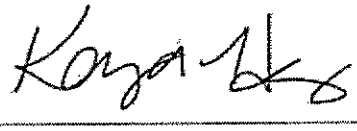


*Basil Raad*

## Witnesses



*Paula Hooper*



*Keya Henry*

Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-500
Austin, TX 78701
512-305-8000

# Inspection Report

## Facility Information

Name: *PRIMERA PROFESSIONAL PHARMACY* License Number:
Class of License: *AS*

## Inspection Information

Type: *Compliance* Purpose: *Pre-Inspection*
Date: *03/10/2022* Arrival Time: *2:10 PM* Departure Time: *3:10 PM*
Action Taken: *Pre-Inspection*

## Pre-Inspection Checklist

| | |
|---|---|
| 1. The prescription department has adequate space for the size and scope of the pharmaceutical services provided by the pharmacy. | *Yes* |
| 2. Fixtures (i.e. shelving, countertops, etc.) for the storage of drugs, equipment, and supplies necessary to operate a pharmacy are installed. | *Yes* |
| 3. Electrical supply exists. | *Yes* |
| 4. A sink with hot and cold running water available exclusive of the restroom facilities. | *Yes* |
| 5. Pharmacy arranged in an orderly fashion and kept clean. | *Yes* |
| 6. The prescription department is complete and contains the following required equipment and supplies including, but not limited to: | *Yes* |
| 6a. data processing system including a printer or comparable equipment; | *Yes* |

Comment

*Liberty Computer Software*

| | |
|---|---|
| 6b. refrigerator to be maintained within a range compatible with the proper storage of drugs requiring refrigeration; | *Yes* |
| 6c. adequate supply of child-resistant, light-resistant, tight, and, if applicable, glass containers; | *Yes* |
| 6d. adequate supply of prescription labels with name, address, and telephone number of the pharmacy; | *Yes* |
| 6e. appropriate equipment necessary for the proper preparation of prescription drug orders; | *Yes* |
| 6f. metric-apothecary weight and measure conversion charts; | *Yes* |
| 6g. if the pharmacy serves the public, the word "pharmacy" or similar word or symbol, as determined by the board, is displayed in a prominent place on the front of the pharmacy. | *Yes* |
| 7. A reference library is on site and current: | *Yes* |

PRIMERA PROFESSIONAL PHARMACY

## Pre-Inspection Checklist *(continued)*

| | |
|---|---|
| 7a. Texas Pharmacy Laws and Regulations (publication year: _____)<br>Publication Year: *2021* | *Yes* |
| 7b. Drug Interactions Reference (publication year: _____)<br>Publication Year: *Online* | *Yes* |
| Comment: *Facts and Comparisons Online* | |
| 7c. General Information Reference (publication year: _____)<br>Publication Year: *Online* | *Yes* |
| Comment: *Facts and Comparisons Online* | |
| 7d. Chapter 795 of the USP/NF concerning Pharmacy Compounding Non-Sterile Preparations (if the pharmacy is compounding non-sterile preparations) | *Yes* |
| 7e. General reference text on veterinary drugs (if the pharmacy dispenses veterinary prescriptions) | *Not Applicable* |
| 7f. Basic Antidote Information and telephone number of the nearest Regional Poison Control Center. | *Yes* |
| 8.If the pharmacy is compounding sterile preparations, the following references are also required: | *Yes* |
| 8a. United States Pharmacopeia/National Formulary or USP Pharmacist's Pharmacopeia containing USP Chapter 797, Pharmaceutical Compounding Sterile Preparations | *Yes* |
| 8b. Chapter 71 of the USP/NF concerning Sterility Tests | *Yes* |
| 8c. Chapter 85 of the USP/NF concerning Bacterial Endotoxins Test | *Yes* |
| 8d. Chapter 1163 of the USP/NF concerning Quality Assurance in Pharmaceutical Compounding | *Yes* |
| 8e. Handbook on Injectable Drugs (publication year: _____)<br>Publication Year: *Online* | *Yes* |
| 8f. Specialty reference text appropriate for the scope of pharmacy services provided by the pharmacy. (e.g., if the pharmacy prepares hazardous drugs, a reference text on the preparation of hazardous drugs) | *Not Applicable* |
| 9. Security Requirements can be met to assure the pharmacy will be locked by key, combination, or other mechanical or electronic means to prohibit unauthorized access when a pharmacist is not on-site. | *Yes* |

PRIMERA PROFESSIONAL PHARMACY

## Pre-Inspection Checklist *(continued)*

10. Pharmacy has basic alarm system with the off-site monitoring and perimeter and motion sensors. (Alarm must be activated). *If your city requires an alarm permit, provide a copy of the permit. — *Yes*

Comment

*ADT alarm service provider*

11. Written policies and procedures for the pharmacy's security system that meet the requirements of Rule 291.33(b)(2)(E) — *Yes*

12. An area suitable for confidential patient counseling, if the pharmacy serves the general public — *Yes*

13. If compounding sterile preparations, the pharmacy has controlled area that meets the requirements in Rule 291.133 (d)(6)(A) if the pharmacy is compounding low-risk and medium-risk preparations or Rule291.133(d)(6)(B) if high-risk preparations are being compounded. — *Yes*

14. Certified primary engineering control device (e.g., laminar airflow work benches, biological safety cabinets, compounding aseptic isolators, and compounding aseptic containment isolators). — *Yes*

15. Certified clean room(s) (e.g. ante area, buffer area). — *Yes*

Comment

*Clean & PEC certified 03/01/2022*

Verify Owner/Owner's Representative ID — *Not Applicable*

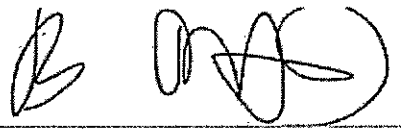
Verify PIC ID — *Yes*

Name: *Basil Raad* Title: *PIC/Owner*

## Signatures

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted.

- Items designated as "Refer to Legal" must be rectified immediately. In addition, the matter discovered during the inspection and deemed to be a serious violation by the inspector will be referred to the Legal Division for review and possible disciplinary action; and
- Items designated as "Warning Notice" must be corrected by the deadline noted to ensure compliance with the laws and rules governing the practice of pharmacy (Note: A "Warning Notice" is issued for a minor violation, and does not equate to disciplinary action).



*Basil Raad*

PRIMERA PROFESSIONAL PHARMACY

Signatures *(continued)*

Keya Henry

# TEXAS STATE BOARD OF PHARMACY

## Pharmacist in Charge Attestation:

**I hereby attest the following statements are true and accurate (initial each statement below):**

PM — I am the Pharmacist-in-Charge (PIC) of *PRIMERA PROFESSIONAL PHARMACY*, pharmacy license number *34197*, and I ☑ was/ ☐ was not present during a Compliance Inspection conducted by a Texas State Board of Pharmacy Compliance Officer/Inspector on *09/16/2022*.

PM — I received and reviewed the Notice of Inspection, Inspection Report, and Warning Notice (if applicable) issued by the Compliance Officer/Inspector.

PM — I reviewed the document titled Texas State Board of Pharmacy "Red Flags" Checklist for Pharmacies YOU MIGHT BE A PILL MILL IF.

N/A — If applicable, the Warning Notice issued contains *0* deficiencies which may require corrections to resolve. I affirm that each of the deficiencies will be corrected by the date noted on the Warning Notice.

PM — I was present and completed this Attestation during the Compliance Inspection.

If not completed during the Compliance Inspection, please email this completed form to the TSBP Compliance Inspector for your area or to inspections@pharmacy.texas.gov within 7 days of the date of the inspection.

Signed: _____ Date: *09/16/2022*

Printed Name: *Paula Hooper* License No.(if applicable): *45649*

**Texas State Board of Pharmacy**
**"Red Flags" Checklist for Pharmacies**
**YOU MIGHT BE A PILL MILL IF...**

*Check all that apply:*

| | |
|---|---|
| | (1) Your pharmacy fills a discernable pattern of prescriptions for prescribers who write essentially the same prescriptions for numerous persons, indicating a lack of individual drug therapy |
| | (2) Your pharmacy operates with limited hours of operation or closes after a certain threshold of controlled substance prescriptions are dispensed, and has overall low prescription dispensing volume. |
| | (3) Prescriptions presented to the pharmacy are for controlled substances with popularity as street drugs, such as opiates, benzodiazepines, muscle relaxants, psychostimulants, and/or cough syrups, or any combination of these drugs. |
| | (4) The prescriptions for controlled substances contain nonspecific or no diagnoses. |
| | (5) The prescriptions are commonly for the highest strength of the drug and/or for large quantities. |
| | (6) Dangerous drugs or OTC products (such as multi-vitamins or laxatives) are added to the controlled substance prescriptions, maintaining relatively consistent 1:1 ratio of controlled substances to dangerous drugs and/or OTC products dispensed as prescriptions. |
| | (7) Prescriptions are authorized by the same prescriber with what appears to be different handwriting on the hardcopy prescription drug order forms. |
| | (8) Upon contact with the prescriber's office, you are unable to engage in comprehensive discussion with the actual prescriber, or he/she is unconcerned about your apprehensions regarding his/her prescribing practices or unwilling to provide additional information, such as treatment goals and/or prognosis with prescribed drug therapy. |
| | (9) You rely solely on the prescriber's representation, or on the representation of the individual answering the phone at the number on the prescription, that prescriptions are legitimate. |
| | (10) The prescriber's clinic is not registered as a pain management clinic by the Texas Medical Board, despite routinely receiving prescriptions from the prescriber foropiates, benzodiazepines, and/or muscle relaxants. |
| | (11) Drugs prescribed are inconsistent with the prescriber's area of practice. |
| | (12) The prescriber of the drugs is located a significant distance from your pharmacy. |
| | (13) The prescriber has been subject to disciplinary action by the licensing board, had his/her DEA registration removed, or been subject to criminal action. |
| | (14) The Texas PMP system indicates that persons are obtaining prescriptions for the same drugs from multiple prescribers or that persons are filling prescriptions for the same drugs at multiple pharmacies. |
| | (15) The person's address is a significant distance from your pharmacy and/or from the prescriber's office. |
| | (16) Multiple persons with the same address present prescriptions from the same prescriber. |
| | (17) Persons pay with cash or credit card more often than through insurance. |
| | (18) Persons presenting controlled substance prescriptions are doing so in such a manner that varies from seeking routine pharmacy services (e.g., willing to wait in long lines to receive drugs, persons arrive in the same vehicle with prescriptions from same prescriber, one person presents to pick up prescriptions for multiple others, persons refer to drugs by "street names" and/or comment on drug's color, persons seek early refills, persons travel from outside reasonable trade area of pharmacy). |
| | (19) Your pharmacy charges and persons are willing to pay more for controlled substances than they would at nearby pharmacies. |
| | (20) Your pharmacy routinely orders controlled substances from more than one drug supplier, or your pharmacy has been discontinued by a drug supplier related to controlled substance orders. |
| | (21) Sporadic and non-consistent dispensing volume (including zero dispensing) varies from day to day and week to week, and your pharmacy does not maintain operational hours each week on Monday through Friday. |
| | (22) Your pharmacy employs or contracts security personnel during operational hours to prevent problems. |
| | (23) Your pharmacy has been previously warned or disciplined by the Texas State Board of Pharmacy for inappropriate dispensing of controlled substances (i.e., corresponding responsibility). |

If you checked any of the above items, you should review the laws and rules regarding corresponding responsibility and non-therapeutic dispensing, especially Board rule §291.29, in the law book or on our website: www.pharmacy.texas.gov (click on Texas Pharmacy Rules and Laws). Additional educational material is available at: http://www.pharmacy.texas.gov/Nontherapeutic.asp. Failure of pharmacies and pharmacists to detect patterns of inappropriate dispensing of prescription drugs is unprofessional practice and constitutes grounds for disciplinary action.

Updated 2/2018

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

**Section 1: Pharmacy/Wholesaler Information**

Name of Pharmacy/Wholesaler: Primera Professional Pharmacy

Pharmacy/Wholesaler License # (if applicable): n/a

Physical Address: 3745 Highway 6

City: Sugar Land State: TX Zip: 77478

Mailing Address (If different from physical address): see above

City: State: Zip:

Telephone: 832-562-3993 Website: www.primerarx.com

Licensing Company Email: admin@primerarx.com

**Section 2: Personal Information**

First: Paula Middle: Rudel Last: Hooper

Alias(es, nicknames, name changes, etc.): Paula Rudel, Paula Jean Rudel

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted] Highway 6

City: Sugar Land State: TX Zip: 77478

Telephone: 832-562-3993 Email: paula.hooper@primeracompounding.com

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✓ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| University of Houston College of Pharmacy | | | 08/2002-05/2007 | |
| Address | | City | State | Zip |
| 4349 Martin Luther King Boulevard | | Houston | TX | 77204 |
| Diploma/Degree obtained, if any | | | | |
| Doctor of Pharmacy | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| University of Houston | | | 05/1998-05/2002 | |
| Address | | City | State | Zip |
| 4349 Martin Luther King Boulevard | | Houston | TX | 77204 |
| Diploma/Degree obtained, if any | | | | |
| n/a | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| Wharton County Junior College | | | 08/1987-05/1989 | |
| Address | | City | State | Zip |
| 901 Boling Highway | | Wharton | TX | 77488 |
| Diploma/Degree obtained, if any | | | | |
| Associates in Applied Arts | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| Brazos High School | | | 08/1983-05/1987 | |
| Address | | City | State | Zip |
| 16621 HWY 36 S | | Wallis | TX | 77485 |
| Diploma/Degree obtained, if any | | | | |
| High School Diploma | | | | |
| School Name | | | From - To (MM/YY – MM/YY | |
| Address | | City | State | Zip |
| Diploma/Degree obtained, if any | | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 10/2008-present | [redacted]Walker Lane | Richmond | TX | 77406 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Primera Professional Pharmacy | | | 03/22-Present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 3745 Highway 6 | | Sugar Land | TX | 77478 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 832-562-3993 | Pharmacist in Charge | | 1,224 | |
| **Description of Duties** | | | | |
| Pharmacist-In-Charge (PIC) responsibilities as prescribed by State regulations, ensure regulatory compliance for all areas of responsibility, compound Sterile and non-sterile pharmaceutical preparations | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Choice Specialty Pharmacy | | | 03/19-03/20 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 1403 Highway 6, Suite 700A | | Sugar Land | TX | 77478 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 832-944-6112 | Pharmacist in Charge | | 6,008 | |
| **Description of Duties** | | | | |
| Pharmacist-In-Charge (PIC) responsibilities as prescribed by State regulations, ensure regulatory compliance for all areas of responsibility, compound Sterile and non-sterile pharmaceutical preparations | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✓ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✓ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✓ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | ✓ | |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # 6 . Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| 04/23/2021 | 06/09/2021 | AR | Little Rock | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| 2021CE-026 | Arkansas State Board of Pharmacy |

| Reason/Charge |
|---|
| Respondent failed to acquire the number of continuing hours required by Board regulations |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| Paula Hooper | Submit required CE and pay $1500.00 penalty |

| Name of Business/Industry/Entity |
|---|
| Paula Hooper |

**Provide explanation below:**

I was short a total of 15 hours of continuing education hours. The charge was not constituted as a disciplinary action, but rather an informal resolution of charges. The Board and I agreed that I would submit the required CE and pay the monetary penalty of $1500.00 to the board. Please see attached Consent Agreement.

Original Signature (electronic, copies or stamps not accepted)

10/26/2022
Date

I, Paula Hooper, **certify that as the designated representative for**

Primera Professional Pharmacy,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. PRH I am at least 21 years of age;
3. PRH I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. PRH I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. PRH I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. PRH I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. PRH I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Paula Hooper

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/26/22

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Paula Hooper

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/26/2022

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Texas, ss. County of Fort Bend

I, Paula Hooper, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

10/26/22

**Date**

Subscribed and Sworn to before me this 26th day of October.

**Notary Public Signature**

JAMIE LENARD
Notary ID #132095490
My Commission Expires
July 19, 2023

# Arkansas State Board of Pharmacy

322 South Main Street, Suite 600 Little Rock, AR 72201
P: 501.682.0190 F: 501.682.0195
asbp@arkansas.gov • www.pharmacyboard.arkansas.gov
John Clay Kirtley, Pharm.D., Executive Director


June 16, 2021

Paula Hooper
29103 Walker Lane
Richmond, TX 77406

RE: Signed Consent Agreement

Dear Sir/Madam:

Attached is a copy of the signed consent agreement that was approved by the Board. Please contact the Board if you have any questions.

Sincerely,

Luke Daniel
General Counsel

BEFORE THE ARKANSAS STATE BOARD OF PHARMACY

IN THE MATTER OF
Paula Hooper
LICENSE NUMBER: PD12462 CASE NUMBER: 2021CE-026

CONSENT AGREEMENT

WHEREAS, Respondent Paula Hooper is licensed as a pharmacist and holds license number ; PD12462

WHEREAS, Board Regulation 02-06-0003 (b) required that Respondent complete thirty (30) hours of continuing education during 2018-2019, including twelve (12) live contact hours and twelve (12) ACPE hours;

WHEREAS, Respondent failed to acquire the number of continuing hours required by Board regulations;

WHEREAS, Respondent was short a total of 15 hours, which includes 12 general continuing education hours and 3 live continuing education hours, and is required to make up twice the hours missed per category;

WHEREAS, Respondent may be charged with violations of Board Regulation 02-06-0003 (b);

WHEREAS, Respondent makes no admission of guilt but wishes to resolve these charges informally. Respondent and the Board therefore agree that this Agreement shall not constitute disciplinary action, but rather an informal resolution of these charges. Respondent expressly waives his/her right to an administrative hearing and consents to the terms incorporated into this Agreement. Respondent further consents to the *ex parte* presentation of this Agreement to the Board and agrees that, if the Agreement is not accepted by the Board, the presentation and consideration of this Consent Agreement by the Board shall not constitute a basis for disqualification of the Board or any of its members from further participation in this matter, including a formal hearing; and

WHEREAS, Respondent acknowledges that this Consent Agreement is not effective until its acceptance by the Board, that the Respondent has had the opportunity to consult with legal counsel of his/her own choosing concerning the advisability, meaning and effect of this Consent Agreement, that the Board shall retain jurisdiction to enforce the provisions of this Consent Agreement and that failure to comply with the terms and conditions of this agreement shall be grounds for further disciplinary action in the form of a civil penalty and/or suspension or revocation of Respondent's license, registration, or permit.

THEREFORE, Respondent consents to the following terms in full resolution of this complaint:

1. Respondent willingly agrees and stipulates that they shall successfully complete and deliver documentation to the Board of 30 hours of continuing pharmacy education, of which shall include twice the number of live continuing education hours, (6 hours)

and twice the number of general continuing education hours due (24 hours), due on or before June 1st , 2021; said hours of continuing education shall be in addition to those hours from 2020-2021 that Respondent is required by Board Regulation 02-06-0003 (c) to acquire for renewal of Respondent's pharmacist license for 2022-2023.

2. Respondent shall submit required CE and pay a monetary penalty of $1500.00 to the Board on or before June 1st, 2021.

EXECUTED this 23 day of April, 2021

Respondent

Attorney for Respondent (optional)

And

JOHN CLAY KIRTLEY, PHARM. D
Executive Director
Arkansas State Board of Pharmacy

APPROVED BY THE BOARD this 09 day of June, 2021

ARKANSAS STATE BOARD OF PHARMACY

President

# Nevada State Board Of Pharmacy

(Licensee mailing address for window envelope)

THIS STUB IS YOUR RECEIPT

Date: 03/09/2023
Amount:
License #: 23526

Paula R. Hooper

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Pharmacist
Effective Date:03/09/2023
Expires:09/09/2023

Paula R. Hooper

License #
23526
Temporary

IDENTIFICATION ONLY
DOES NOT MEET POSTING REQUIREMENTS

Trim ID Card to fit your wallet

Cut Here

**NEVADA**

**STATE BOARD OF PHARMACY**

**Pharmacist**

Expires: 09/09/2023
STATUS: Temporary

License Type: Pharmacist
License #: 23526
Effective Date:03/09/2023

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENSED

Paula R. Hooper

**NONTRANSFERABLE**

POST THIS LICENSE PROMINENTLY IN A CONSPICUOUS PLACE

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

**Section 1: General Information**

Pharmacy Name: Primera Professional Pharmacy

NV Pharmacy or Outsourcing facility license # (if applicable): pending

Physical Address: 3745 Highway 6

City: Sugar Land State: TX Zip: 77478

Mailing Address (if different from physical address): see above

City: State: Zip:

Telephone: 832-562-3993 Toll Free # (NAC 639.708, NRS 639.23286): 800-610-2521

Fax: 346-321-4500 Contact Email: admin@primerarx.com

Website: www.primerarx.com

Nevada Business License # (if applicable) n/a

Supervising/Managing Pharmacist Name (NRS 639.220): Paula Hooper

Supervising/Managing Pharmacist NV Pharmacist Registration #: n/a

Name of Person with direct knowledge of compounding procedures: Paula Hooper

Email of Person with direct knowledge of compounding procedures: paula.hooper@primeracompounding.com

Telephone of Person with direct knowledge of compounding procedures: 832-562-3993

**Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)**

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☒ Low ☒ Medium ☒ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ☒ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
n/a

4. Will you be utilizing beyond use dates in excess of USP-797? ☒ Yes ☐ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:
Please see attached, SOP 9.050 Title: Beyond-Use Dating (BUD) of Sterile Compounded Preparations.

6. What laboratory performs this additional testing?
Name: Eagle Analytical
Address: 11111 S. Wilcrest Dr, Suite S1000
City: Houston State: TX Zip: 77099
Telephone: 800-745-8916

7. What is your procedure for visual inspection of compounded sterile products?
The end product is visually inspected and verified by the pharmacist for container leaks, integrity, solution cloudiness or phase separation, appropriate color, and appropriate volume.

8. How often do you perform glove fingertip and medial fill testing?

Gloved Fingertip sampling and media fill testing occurs during initial competency evaluation after garbing, and every 6 months.

9. What is your policy if an employee fails a glove fingertip or media-fill test?

All failures must have a formal investigation completed. See attached, SOP 205.5 Title Invest & Remed in Event Sampling Exceeds Alert of Act

10. Describe your initial and annual training program for all personnel performing sterile compounding:

Initial training for all personnel performing sterile compounding must complete the procedures described in SOP 2.010 Title Employee Training, SOP 2.020 Compounding Personnel Orientation Program

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Please see attached SOP 3.020 titled Cleaning and Maintenance of the Clean Room Facility for the details of the cleaning procedure for our primary and secondary engineering controls.

All hood surfaces are cleaned with sterile 70% Isopropyl Alcohol and non-shedding sterile wipes, then with TX 650 (RTU) Disinfectant from TexQ and non-shedding sterile wipes.

When cleaning the primary and secondary engineering controls, designated tasks are completed daily, weekly, and monthly. Sterile 70% isopropyl alcholol, TX 650 (RTU) disinfectant from TexQ, sterile sporicidal (Peridox RTU from Contec) non-shedding sterile wipes and cleaning supplies, used solely for the primary and secondary engineering controls, are used and stored separate from the cleaning supplies used at the rest of the pharmacy.

12. Who performs the sterile compounding process at your facility?

Pharmacists and pharmacy technicians who completed and passed the sterile compounding training program perform the sterile compounding process at our facility.

13. Who is responsible and accountable for the sterile compounding process at your facility?

The Pharmacist in Charge is responsible and accountable for the sterile compounding process at our facility.

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

Please see attached SOP titled, "Shipping / Delivery Out of State."

| **Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)** | | |
|---|---|---|
| 1. What type of primary engineering controls will you be using in your facility?<br>n/a | | |
| 2. Is your BSC or CACI vented 100% to the outside? | ☐ Yes | ☐ No |
| 3. Do you have a negative pressure buffer room at your facility? | ☐ Yes | ☐ No |
| 4. Will you be compounding with antineoplastic HDs or HD API? | ☐ Yes | ☐ No |
| 5. If yes, are the drugs stored in an externally ventilated, negative pressure room? | ☐ Yes | ☐ No |
| 6. Will you be utilizing a closed system transfer device? | ☐ Yes | ☐ No |
| 7. If yes, list the name of the device: | | |
| 8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers? | | |
| 9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs? | | |

**Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)**

1. List the specific high risk sterile products that your facility compounds:

Ophthalmic products

2. What sterilization methods are utilized at your facility?

0.2 micron sterile filters
Steam sterilizer (autoclave)
Dry heat sterilization

3. Does your facility utilize biological indicators? ☒ Yes ☐ No

4. If yes, describe how they are utilized:

Biological indicators are used to assure the sterilization process.

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Patty Heinz

Name of Person who Completed the Form

VP Operations

Title

Signature (copies or stamps not accepted)

10/26/2022

Date

| Board Use Only | Date Received:_____ Date Approved: _____ Approved By: _____ |
|---|---|

| TITLE: BEYOND-USE DATING (BUD) OF STERILE COMPOUNDED PREPARATIONS | |
|---|---|
| **SOP NUMBER: 9.050** | **VERSION NUMBER: 1.0** |
| Authorized By: | Date: Dept: Pharmacy |
| Written By: Paula Hooper, PharmD, RPh | Date: 02/22/2022 |
| Reviewed By: Basil Raad, RPh | Date: |
| Date Effective: | |

## 1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for determining a beyond-use date (BUD) for sterile compounded preparations.

## 2.0 SCOPE

2.1 This procedure applies to all compounding personnel at Primera Professional Pharmacy

## 3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure and document that all personnel responsible for compounding will comply with this procedure.

## 4.0 REFERENCES

4.1 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.2 USP Current Version <1150> "Pharmaceutical Stability"

## 5.0 DEFINITIONS

5.1 BUD – Beyond-use date

## 6.0 FREQUENCY

6.1 This procedure shall be performed for each compounded preparation.

## 7.0 EQUIPMENT & SUPPLIES

7.1 Appropriate reference materials

## 8.0 GENERAL INFORMATION

8.1 All compounded preparations must have an appropriate BUD.

## 9.0 PROCEDURE

9.1 BUDs shall be assigned based on current drug stability information and sterility considerations.

9.2 Consideration shall be given to all aspects of the finished product including drug reservoir, concentration and storage conditions.

9.3 A reliable method for determining BUDs shall be established, including laboratory testing of product stability, pyrogenicity and chemical content when necessary.

9.3.1 **Physical stability** of the compounded preparation shall signify that the preparation has retained the original physical properties of the preparation, such as appearance, palatability, uniformity, dissolution and suspendability.

9.3.2 **Chemical stability** of the compounded preparation shall signify that each active ingredient has retained its chemical integrity and labeled potency within specified limits.

9.3.3 **Microbiological stability** of the compounded preparation shall signify that sterility or resistance to microbial growth has been retained according to the specified

| TITLE: BEYOND-USE DATING (BUD) OF STERILE COMPOUNDED PREPARATIONS | |
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requirements. Antimicrobial agents that are present shall retain their effectiveness within the specified limits.

9.3.4 Additional factors that affect the stability of the final preparation, and shall be considered, include pH, temperature, solvent, light, air, humidity, particle size, ionic strength, dielectric constant, polymorphism, crystallization, vaporization and absorption.

9.4 In the absence of stability information that is applicable to a specific drug and preparation, the following maximum BUDs are recommended for sterile compounded preparations packaged in tight, light-resistant containers and stored at controlled room temperature, refrigerator, or freezer when indicated:

9.4.1 Category 1 CSPs that may be prepared in an unclassified segregated compounding area, and does not require sterility testing.

9.4.2 Category 2 CSPs are dictated by the method of sterilization, whether or not a sterility test is performed, passed, and the temperature of the preparation.

**9.4.1. For Category 1 CSPs, the BUDs are shown in Table 10 from USP <797>.**

**Table 10. BUDs for Category 1 CSPs**

| | Storage Conditions | |
|---|---|---|
| | Controlled Room Temperature (20°-25°) | Refrigerator (2°-8°) |
| BUD | ≤12 hours | ≤24 hours |

**9.4.2. For Category 2 CSPs, The BUDs are shown in Table 11 from USP <797>.**

Table 11. BUDs for Category 2 CSPs

| Preparation Characteristics | | Storage Conditions | | |
|---|---|---|---|---|
| Compounding Method | Sterility Testing Performed and Passed | Controlled Room Temperature (20°-25°) | Refrigerator (2°-8°) | Freezer (-25° to -10°) |
| Aseptically Processed | No | Prepared from one or more nonsterile starting components(s): 1 day | Prepared from one or more nonsterile starting component(s): 4 days | Prepared from one or more nonsterile starting component(s): 45 days |
| Aseptically Processed | No | Prepared from only sterile starting components: 4 days | Prepared from only sterile starting components: 10 days | Prepared from only sterile starting components: 45 days |
| Aseptically | Yes | 30 days | 45 days | 60 days |

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| Processed CSPs | | | | |
|---|---|---|---|---|
| Terminally sterilized CSPs | No | 14 days | 28 days | 45 days |
| Terminally sterilized CSPs | Yes | 45 days | 60 days | 90 ays |

**9.4.3.** Multiple-dose CSPs are prepared as Category 2 CSPs. After a multiple-dose container is initially entered or punctured, itmust not be used for longer than the assigned BUD or 28 days, if supported by antimicrobial effectiveness testing results, whichever is shorter.

9.5 Applicable publications shall be referenced to obtain relevant stability, compatibility and degradation information regarding a drug or its congeners.

9.5.1 A compounding pharmacy reference library will be available for compounding laboratory personnel so they may access critical information in a timely manner.

9.5.2 Referenced publications shall be available for compounding personnel. The reference library may include, but not be limited to, the following publications:

9.5.2.1 Facts and Comparisons

9.5.2.2 Handbook on Injectable Drugs (ASHP)

9.5.2.3 Handbook on Injectable Drugs (Trissel)

9.5.2.4 Handbook of Pharmaceutical Excipients

9.5.2.5 International Journal of Pharmaceutical Compounding

9.5.2.6 Internet access to PubMed for literature searches

9.5.2.7 Martindale: The Extra Pharmacopoeia

9.5.2.8 Micromedex Electronic Drug Reference

9.5.2.9 Pharmaceutical Calculations

9.5.2.10 Pharmaceutical Dosage Forms and Drug Delivery Systems

9.5.2.11 Policies and procedures

9.5.2.12 Principles of Sterile Product Preparation (ASHP)

9.5.2.13 Quality Control/Assurance documentation logs

9.5.2.14 Remington: The Science and Practice of Pharmacy

9.5.2.15 State law books and guidelines regarding compounding

9.5.2.16 The Merck Index

9.5.2.17 United States Pharmacopeia or USP Pharmacists' Pharmacopeia

9.5.3 All periodical subscriptions that pertain to compounding pharmacy shall be kept in the reference library.

9.6 The pharmacy may choose to perform potency assays on products with a narrow therapeutic index, where close monitoring or dose titration is required to ensure therapeutic effectiveness and to avoid toxicity, where a theoretically established BUD is

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supported by only marginal evidence or where significant margin of safety cannot be verified.

## 10.0 ATTACHMENTS

10.1 Attachment 1 – Table 10, Table 11

## 11.0 HISTORY

| Version Number | Date Effective | Description of Change | Change Request Number |
|---|---|---|---|
| 1.0 | | New SOP. | |

Remainder of this page intentionally left blank.

| TITLE: BEYOND-USE DATING (BUD) OF STERILE COMPOUNDED PREPARATIONS | |
|---|---|
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**Category 1 CSPs** that may be prepared in an unclassified segregated compounding area, and does not require sterility testing.

**Category 2 CSPs** are dictated by the method of sterilization, whether or not a sterility test is performed, passed, and the temperature of the preparation.

1. For Category 1 CSPs, the BUDs are shown in Table 10 from USP <797>.

**Table 10. BUDs for Category 1 CSPs**

| | Storage Conditions | |
|---|---|---|
| | **Controlled Room Temperature (20°-25°)** | **Refrigerator (2°-8°)** |
| BUD | ≤12 hours | ≤24 hours |

2. For Category 2 CSPs, The BUDs are shown in Table 11 from USP <797>.

Table 11. BUDs for Category 2 CSPs

| Preparation Characteristics | | Storage Conditions | | |
|---|---|---|---|---|
| **Compounding Method** | **Sterility Testing Performed and Passed** | **Controlled Room Temperature (20°-25°)** | **Refrigerator (2°-8°)** | **Freezer (-25° to -10°)** |
| Aseptically Processed | No | Prepared from one or more nonsterile starting components(s): 1 day | Prepared from one or more nonsterile starting component(s): 4 days | Prepared from one or more nonsterile starting component(s): 45 days |
| Aseptically Processed | No | Prepared from only sterile starting components: 4 days | Prepared from only sterile starting components: 10 days | Prepared from only sterile starting components: 45 days |
| Aseptically Processed CSPs | Yes | 30 days | 45 days | 60 days |
| Terminally sterilized CSPs | No | 14 days | 28 days | 45 days |
| Terminally sterilized CSPs | Yes | 45 days | 60 days | 90 days |

Multiple-dose CSPs are prepared as Category 2 CSPs. After a multiple-dose container is initially entered or punctured, itmust not be used for longer than the assigned BUD or 28 days, if supported by antimicrobial effectiveness testing results, whichever is shorter.

| Section Name: Facility and Personnel Monitoring | SOP Name: Investigation and Remediation in the Event Sampling Exceeds Alert or Action Levels |
|---|---|
| | Date of Initial: 08/02/21 |
| SOP/Version #: 205.5 | Last Revision/Review: 09/16/21 |

## 1.0 Purpose Statement

This SOP defines what an excursion is and establishes when and how action is taken to regain a microbial state of control. It outlines a logical set of information sought during initial and ongoing investigations of microbial excursions in environmental and personnel sampling. No document can provide all-encompassing guidance for specific investigation and remediation of new or ongoing excursions, but Matrix of Actions for First-Time Excursions; F-205.b and Matrix of Actions for Consecutive and Repeat Excursions; F-205.c provide actions to be considered in these instances. This SOP also provides the general guidance followed in any investigation as well as parameters that are included and the documentation of these actions.

## 2.0 Policy Statements

2.1 It is not alarming and is, in fact, expected that small numbers of CFUs (below designated action levels) will be found in ISO 7 and 8 environments and even 1 CFU in ISO 5 spaces.

2.2 The occurrence of consistent 0 CFU returns in viable air, surface, or gloved fingertip sampling prompts a high degree of suspicion that sampling procedures and activities are flawed.

2.3 USP 797 (2019) requires the identification of growth in viable air and surface samples when growth exceeds the action level (as specified for each type of sampling per USP 797).

2.4 An excursion is said to exist under the following conditions:

2.4.1 Action level: When the CFUs counted in any sample (air, surface, gloved fingertip) exceed the established action level for the type of sampling. Refer to specific SOPs on each type of sampling for action levels. All sections of Facility and Personnel Sampling Action Report; F-205.a must be completed.

2.4.2 Alert level: When the CFUs counted in any sample (air, surface, gloved fingertip) exceed the established alert level but are below the established action level for the type of sampling. Refer to specific SOPs on each type of sampling for alert levels. Facility and Personnel Sampling Action Report; F-205.a is used as a tool to evaluate factors that could be contributing to elevated microbial levels. The use of alert levels is not required by USP 797 but is a best practice recommendation.

2.4.3 Organism of concern: When the CFUs counted in any sample (air, surface, gloved fingertip) are *below* the established alert and action levels for the type of sampling, but an organism of concern is recovered. Organisms of concern are certain gram-positive spore-forming rods, certain gram-negative rods, coagulase-positive *Staphylococcus,* and some yeasts and molds. Facility and Personnel Sampling Action Report; F-205.a is used as a tool to evaluate factors that could be contributing to recovery of organisms that are not typically seen as part of the facility's microbial population or should be further investigated if they are being repeatedly recovered in the facility.

2.5 There are three types of excursions.

2.5.1 First excursion: The very first time a location has an EM excursion.

2.5.2 Consecutive excursion: When a location has back-to-back EM excursions, either organisms of concern or an exceeded action level.

2.5.3 Repeat excursion: When a location has an excursion again, either organisms of concern or an exceeded action level, but the excursions have not occurred consecutively.

2.6 Facility has established a contractual relationship with a properly licensed pharmaceutical microbiology laboratory that has been accredited to ISO 17025 and is registered with the FDA.

2.7 Plates are sent to the laboratory for identification of growth for the following reasons:

2.7.1 Anytime an established action level is exceeded for viable air and surface samples, the growth is identified as required by USP 797.

2.7.2 Consideration may be given to performing identifications when an established alert level in a specific location is exceeded more than once. Gathering additional information may be helpful in identifying the source of the microorganisms.

2.7.3 If sample counts are below the action and alert levels but an organism of concern is recovered, identification of the microorganism may be sought to provide additional information about an unexpected change in work practices or facility control.

## 3.0 Reference Documents

3.1 Internal documents

3.1.1 Facility and Personnel Sampling Action Report; F-205.a

3.1.2 Matrix of Actions for First-Time Excursions; F-205.b

3.1.3 Matrix of Actions for Consecutive and Repeat Excursions; F-205.c

3.1.4 Quality Management Considerations in Environmental Monitoring and Personnel Sampling; SOP-204

3.1.5 Surface Sampling; SOP-202

3.1.6 Viable Air Sampling; SOP-200 and related forms

3.1.7 Gloved Fingertip Sampling; SOP-408

3.1.8 Personnel Aseptic Media-Fill Testing and Process Verification; SOP-402

3.1.9 Conduct of Personnel in Controlled Areas and Aseptic Technique Overview; SOP-412

3.2 External resources

3.2.1 United States Pharmacopeial Convention, Inc. USP <797> Pharmaceutical Compounding—Sterile Preparations. 2019 version (postponed indefinitely).

3.2.2 United States Pharmacopeial Convention, Inc. <1116> Microbial Control and Monitoring of Aseptic Processing Environments. 2018.

## 4.0 Specific Work Practices and Procedure Descriptions

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4.1 When an excursion is realized, the following forms are used: Facility and Personnel Sampling Action Report; F-205.a and Matrix of Actions for First-Time Excursions; F-205.b. For a consecutive or repeat excursion, use Matrix of Actions for Consecutive and Repeat Excursions; F-205.c.

4.1.1 If the number of CFUs recovered exceeds the action level, all sections of F-205.a are completed.

4.1.2 If the number of CFUs recovered exceeds the alert level but falls below the action level, F-205.a is used to document the evaluation that must occur.

4.1.2.1 Follow-up sampling is not required but may be considered during the first occasion that a sample location alert level is exceeded (but below the action level).

4.1.2.2 In the event an alert level is exceeded during two consecutive samplings for a given location, an investigation, remediation, and resampling are required.

4.1.3 If the number of CFUs recovered is below the alert level (if applicable) or below the action level but an organism of concern is recovered, F-205.a may be used to determine the possible source of the microorganism and identify any work practice changes.

4.2 F-205.a is used to guide the investigation and to document actions. By completing the first section of F-205.a, the appropriate information is collected, identifying the proper actions to be taken as described on F-205.b.

4.3 Take the actions as outlined on F-205.b based on whether the sample is a viable air, surface, or gloved fingertip sample and the ISO classification of the space.

4.4 Additional actions may be required beyond the actions specified in F-205.b if the first set of remedial actions does not reestablish a microbial state of control. Follow F-205.c.

4.5 Continue completing F-205.a as information becomes available.

4.6 The investigation described on F-205.a includes identification and documentation of any or all of the following:

4.6.1 Type of sample and conditions under which sampling occurred

4.6.2 Type of excursion

4.6.3 Verification that activities related to sampling were performed correctly

4.6.4 Microbial control actions taken since sampling and before receiving results

4.6.5 Evaluation of certification reports, work logs (pressure, cleaning, humidity, etc.), competencies

4.6.6 Review of the environmental sampling results, which is to include the following questions:

4.6.6.1 Was growth isolated to one location?

4.6.6.2 Was growth found in adjacent sites?

4.6.6.3 If so, was the organism the same in contiguous sites?

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4.6.7 Evaluation of historical growth trends and determination of the frequency of the organism's recovery, which is to include the following questions:

4.6.7.1 Was the location positive for this growth in last 6 months?

4.6.7.2 Has the location been retested previously?

4.6.7.3 Has the employee had other positive findings?

4.6.7.4 If so, what were they?

4.6.8 Review of the microbiological results, which is to include the following questions:

4.6.8.1 Was the typical reservoir for the microbe or microbes identified?

4.6.8.2 What is the typical reservoir?

4.6.8.3 Was the excursion found close to a location that would be considered a typical reservoir?

4.7 All excursions require remediation, and the plan of remediation is documented on F-205.a.

4.7.1 It may take several follow-up actions and samples to identify, remediate, and bring the sample location back into a state of control.

4.7.2 Those initial and follow-up actions and their results are documented on the form.

4.7.3 The excursion and any follow-up action must be concluded, and the date that the remediation plan is closed must be documented and reviewed by the designated person(s).

4.8 Any additional aspects related to the excursion that are included in the investigation must be thoroughly documented, including dates of action, specific action taken, and the outcome of the actions.

## 5.0 Documentation Elements

5.1 When using Facility and Personnel Sampling Action Report; F-205.a, consider the following:

5.1.1 Any line items that are not required or used must be checked as not applicable or an explanation given.

5.1.2 Any action level requires a complete investigation, which is documented by completing Section 2 of the form; and a specific plan of remedial action must be developed, executed, and documented in Section 3 of the form.

5.1.3 Serial documentation of actions and outcomes must be documented on page 4 of the form.

5.2 Additional pages may be attached if needed, and the added pages must be clearly numbered.

5.3 The dates when the investigation and remediation are officially closed must be documented on the form and signed by the designated person(s).

| | |
|---|---|
| **Section Name:** Facility and Personnel Monitoring | **SOP Name:** Investigation and Remediation in the Event Sampling Exceeds Alert or Action Levels |
| **SOP/Version #:** 205.5 | **Last Revision/Review:** 09/16/21 |

## Section 1: Initial Investigation Actions Taken

**Action began at:** ☐ Interim read: _____ day or ☐ Final read

**Type of environmental sample:** ☐ **Viable air sampling (VAS)** ➡ ☐ Single sample or ☐ Multiple samples

Check all that apply: ☐ ISO 5 ☐ ISO 7 ☐ ISO 8 ☐ Non-ISO classified ☐ Negative space ☐ Positive space

Performed under which conditions: ☐ Static ☐ Dynamic

Describe specific location(s) from ESP:_____ Date sampled:_____

☐ **Surface sampling (SS)** ➡ ☐ Single sample or ☐ Multiple samples

Check all that apply: ☐ ISO 5 ☐ ISO 7 ☐ ISO 8 ☐ Non-ISO classified ☐ Negative space ☐ Positive space

Performed under which conditions: ☐ Static ☐ Dynamic

Describe unit(s) location based on ESP:_____ Date sampled:_____

**Type of personnel sample:** sampled ☐ randomly or ☐ during predetermined testing occurrence

☐ ***Initial* GFS** ➡ # CFU L hand: ____ R hand: ____ Date sampled: _____

☐ ***Ongoing* GFS** (during compounding) ➡ # CFU L hand: ____ R hand: ____ Date sampled: _____

☐ ***Surface sample*** (during compounding) ➡ # CFU L hand: ____ R hand: ____ Date sampled: _____

☐ ***Media-fill unit (MFU)*** ➡ # units made: _____ # units positive: _____ Date units prepared: _____

### Type of excursion:

☐ **Below action level AND organism of concern** (see SOP-205)

☐ **Alert level exceeded:** If alert level is exceeded but the action level is not, then perform an evaluation of appropriate facility engineering controls, personnel, work practice changes, and environmental factors that could be causing this increase in personnel or environmental findings in an effort to regain microbial control. Document review, conclusions, and actions taken.

☐ **Action level exceeded:** Complete all sections of this form

### Complete the following actions, and document additional information in the space provided below:

1. Date pharmacy manager notified:_____
2. Was there evidence that incubated samples/MFUs were exposed/leaking during incubation? ☐ Yes ☐ No

### Send samples for microbial identification:

☐ N/A (if alert level triggered and decision made not to send for ID)

☐ Digital image taken of each sample/MFU at end of incubation if action level was exceeded. By:_____

☐ Name and contact info for laboratory performing ID:_____

☐ Completed documentation and prepared units in packaging per lab instruction. By:_____

☐ Transport to lab via: ☐ Hand delivered ☐ Third-party carrier:_____Tracking #:_____

Expected delivery:_ _____

*Areas in red must be addressed in Section 3: Plan of Remediation*

**Microbiological results:** ☐ N/A (if alert level and no ID performed) ☐ Results attached (number pages): _____)

Date results received:_____

What is the typical reservoir for the microbe or microbes identified?_____

Was the location of the excursion in close proximity to the location of the typical reservoir? ☐ Yes ☐ No

Has this organism(s) been found at this location previously? ☐ Yes ☐ No

## Section 2: Additional Investigation Actions Taken

1. **Were there additional microbial control provisions that have occurred between when the sampling occurred and the microbial results were received?** ☐ Yes ☐ No

   If yes, describe those microbial control provisions:_____

2. **Was certification documentation of SEC/PEC associated with samples reviewed?** ☐ Yes ☐ No

   Did the review identify any discrepancies or issues that were previously unidentified? ☐ Yes ☐ No

   If yes, describe the discrepancies: _____

3. **Were documentation/logs of relevant work practices associated with the finding reviewed?** ☐ Yes ☐ No

   a. Based on review of documentations and staff interviews, was correct procedure followed?

| | | | |
|---|---|---|---|
| ☐ GFS<br>☐ Yes ☐ No | ☐ MFU<br>☐ Yes ☐ No | ☐ VAS<br>☐ Yes ☐ No | ☐ SS<br>☐ Yes ☐ No |

   b. Check all that apply, and dates checked:

   ☐ Cleaning logs; date: _____ ☐ ES logs; date: _____ ☐ Medi-fill logs; date: _____

   ☐ Pressure logs; date: _____ ☐ Temperature records; date: _____ ☐ Humidity records; date: _____

   ☐ Garbing competency; date: _____ ☐ Aseptic technique competency; date: _____

   ☐ Other: _____; date: _____

   c. Did the review identify any discrepancies or issues that were previously unidentified? ☐ Yes ☐ No

   If yes, describe the discrepancies: _____

4. **Was the area recleaned after receiving this microbiological identification?** ☐ N/A ☐ Yes ☐ No

   If yes, what agent(s) was the area treated with? _____

   If yes, when was the area recleaned (include date and time): _____

5. **Was the area taken out of service (compounding suspended)?** ☐ N/A ☐ Yes ☐ No

   If yes, explain what was done: _____

6. **Was the SEC/PEC checked or repaired by authorized personnel?** ☐ N/A ☐ Yes ☐ No

   If yes, what was the date and company, and attach documentation: _____and number pages _____

   If work done inside a PEC or SEC, was area triple cleaned per policy? ☐ N/A ☐ Yes ☐ No

7. **Were assigned BUDs shortened for any period of time?** ☐ N/A ☐ Yes ☐ No

   If yes, explain what was done: _____

*Areas in red must be addressed in Section 3: Plan of Remediation*



Primera COMPOUNDING

**Additional Investigation Actions Taken (continued)**

8. ***Environmental* findings only:** ☐ VAS ☐ SS (other than that taken during compounding)
   a. Was historical trend of sample location reviewed? ☐ Yes ☐ No
   b. Has this location(s) had other positive findings within the last 6 months? ☐ Yes ☐ No
   c. Are there multiple excursions found in the room? ☐ Yes ☐ No
   d. Was the area(s) retested? ☐ N/A ☐ Yes ☐ No
   e. If yes, date of retest: _____
   f. Microbiological results of retest: Date results received: _____ ☐ Number pages attached: _____
   g. Comparison of retest results to initial finding (check all that apply):
      ☐ Below alert level ☐ Below action level ☐ Exceeds alert level ☐ Exceeds action level
      Discussion of findings: _____
      _____

9. ***Personnel* findings only:** ☐ *Initial* GFS ☐ *Subsequent* GFS ☐ MFU ☐ SS (taken during compounding)
   a. Has this employee had other positive findings within the past 2 years? ☐ N/A ☐ Yes ☐ No
   b. If yes, explain: _____
   c. Employee removed from compounding (if subsequent GFS/SS during compounding) ☐ N/A ☐ Yes ☐ No
   d. Were personnel retested after unacceptable results? ☐ N/A ☐ Yes ☐ No
   e. If yes, date of retest: _____
   f. Microbiological results of retest: Date results received: _____ ☐ Number pages attached: _____
   g. Comparison of retest results to initial finding (check all that apply):
      ☐ Below alert level ☐ Below action level ☐ Exceeds alert level ☐ Exceeds action level
      Discussion of findings: _____
      _____
   h. Did personnel successfully complete each of the following (attach forms)?
      Competency assessment for Hand Hygiene and Garbing (F-410.a) ☐ N/A ☐ Yes ☐ No
      Competency assessment for Aseptic Technique (F-410.b) ☐ N/A ☐ Yes ☐ No

10. **Was any personnel retraining conducted?** ☐ N/A ☐ Yes ☐ No
    If yes, explain what was done; attach training logs and other information (total # of pages attached: _____)
    _____

11. **Based on the investigation, were work practices changed?** ☐ N/A ☐ Yes ☐ No
    If yes, which SOPs or forms were changed: _____

_____ _____
Signature of person completing sections 1 and 2 Date sections completed in entirety

## Section 3: Plan of Remediation

Document specific plan, actions taken, outcomes, and follow-up. Any area checked in red in Section 2 must be explained in detail. Each entry (if multiple entries) must be dated and signed by the person making the entry if the plan was not documented during one instance.

## Section 4: Resampling and Results

**Type of environmental resample:**

☐ **Viable air sampling (VAS)** ➡ ☐ Single sample or ☐ Multiple samples

Performed under which conditions: ☐ Static ☐ Dynamic ☐ Static and dynamic for ISO 5

Describe specific location(s) from ESP: _____ Date sampled: _____

☐ **Surface sampling (SS)** ➡ ☐ Single sample or ☐ Multiple samples

Performed under which conditions: ☐ Static ☐ Dynamic ☐ Static and Dynamic for ISO 5

Describe specific location(s) from ESP: _____ Date sampled: _____

**Type of personnel resample:** sampled ☐ randomly or ☐ during predetermined testing occurrence

☐ ***Initial* GFS** ➡ # CFU L hand: _____ R hand: _____ Date sampled: _____

☐ ***Subsequent* GFS** (during compounding) ➡ # CFU L hand: _____ R hand: _____ Date sampled: _____

☐ ***Surface sample*** (during compounding) ➡ # CFU L hand: _____ R hand: _____ Date sampled: _____

☐ ***Media-fill unit (MFU)*** ➡ # units made: _____ # units positive: _____ Date units prepared: _____

**Results:**

☐ **No excursion. Close investigation.**

☐ **Excursion. Follow F-205.c for next steps. Document in section 3.**

_____ _____

Signature of pharmacy manager or designee Date investigation and remediation closed



Primera COMPOUNDING

| TITLE: EMPLOYEE TRAINING | | |
|---|---|---|
| **SOP NUMBER: 2.010** | **VERSION NUMBER: 1.0** | |
| Authorized By: | Date: | Dept: Pharmacy |
| Written By: Patty Heinz | Date: 10/01/2021 | |
| Reviewed By: Basil Raad | Date: | |
| Date Effective: | | |

## 1.0 PURPOSE

1.1 This procedure defines the requirements for new employee orientation and provides a standard method for training.

## 2.0 SCOPE

2.1 This procedure applies to all employees training at Primera Compounding Pharmacy and includes, but is not limited to, compounding training, procedural training and professional development.

## 3.0 RESPONSIBILITY

3.1 It is the responsibility of the Pharmacist-in-charge to provide initial orientation training, ensure that each employee is properly trained and provide the time for employees to remain current with their training.

3.2 Training files shall be maintained by the Pharmacist-in-charge.

## 4.0 REFERENCES

4.1 SOP 1.010 "Policies and Procedures"

4.2 SOP 2.020 "Compounding Personnel Orientation Program"

4.3 SOP 2.030 "Sterile Compounding Personnel Qualification"

4.4 SOP 2.040 "Non-Sterile Compounding Personnel Qualification"

## 5.0 DEFINITIONS

5.1 N/A

## 6.0 FREQUENCY

6.1 Commencement of employment

6.2 Before performing a new procedure

## 7.0 EQUIPMENT & SUPPLIES

7.1 N/A

## 8.0 GENERAL INFORMATION

8.1 Documentation

8.1.1 If group training is conducted, details of the training session should be provided in the individual employee files. The original training record for training activities are filed in the training folder or binder, and copies of the training record are placed in the folders of each trainee on the list.

8.1.2 Job Qualification Records/Resumes are completed as documented evidence that the employee is qualified to perform his/her function.

| TITLE: EMPLOYEE TRAINING | |
|---|---|
| SOP NUMBER: 2.010 | VERSION NUMBER: 1.0 |
| Date Effective: | |

8.2 The Employee Training Record (Attachment 1) is completed and filed whenever an employee participates in any training activity.

8.3 Only qualified personnel may administer training.

## 9.0 PROCEDURE

9.1 Personnel will go through new employee orientation upon employment at Primera Professional Pharmacy (refer to SOP 2.020, "Compounding Personnel Orientation Program").

9.2 Designee will review the organizational chart, quality policy, work and lunch hours, employee benefits and company policies.

9.3 The Pharmacist-in-charge will review specific job performance objectives and job descriptions, give staff introductions and provide a building tour, workspace, keys, and any necessary supplies. The Pharmacist-in-charge will also discuss performance review and facilities issues and will review training requirements.

9.4 For specific task training, the employee will observe the test being performed (where applicable) and will then perform the test under direct supervision. Where appropriate, training checklists will be used to document the training and indicate that the employee is able to complete the tasks independently.

9.5 Additional training or re-training may be necessary for any one of the following reasons: employment development, new technology or equipment, changed position or position requirements or an employee does not meet the requirements of the current position.

9.5.1 The Pharmacist-in-charge is responsible for determining and/or pre-approving specific training needs of each employee on a periodic basis.

9.5.2 All additional training that is not considered continuing education training will be documented on the Employee Training Record (Attachment 1) whenever the employee participates in any of the following training activities:

9.5.2.1 Formal Coursework

9.5.2.2 Seminars

9.5.2.3 Workshops

9.5.2.4 Internal Primera Professional Pharmacy courses

9.5.3 A certificate from an outside training course or seminar may take the place of the Employee Training Record. If no certificate was presented, complete Attachment 1, reference the course material in the "Description of Training" section and retain a copy of the course for reference.

9.6 Employees must receive annual training on quality systems. It is the responsibility of the Pharmacist-in-charge to schedule, perform and document annual training.

9.6.1 New and updated procedure training is covered in the SOP 1.010, "Policies and Procedures."

9.7 Personnel training files shall be maintained by the Pharmacist-in-charge.

## 10.0 ATTACHMENTS

10.1 Attachment 1 – Employee Training Record

| TITLE: EMPLOYEE TRAINING | |
|---|---|
| SOP NUMBER: 2.010 | VERSION NUMBER: 1.0 |
| Date Effective: | |

## 11.0 HISTORY

| Version Number | Date Effective | Description of Change | Change Request Number |
|---|---|---|---|
| 1.0 | | New SOP. | |

Remainder of this page intentionally left blank.

# EMPLOYEE TRAINING RECORD

**Date:** _____

**Training Topic or SOP Number:** _____ **Version:** _____

**SOP Title:** _____

**Trainer Signature:** _____

| Trainee Name (Printed) | Trainee Name (Signature) | Date |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

**Description of Training:** _____

_____

_____

_____

**Reviewed By:** _____ **Date:** _____

| TITLE: COMPOUNDING PERSONNEL ORIENTATION PROGRAM | |
|---|---|
| **SOP NUMBER: 2.020** | **VERSION NUMBER: 1.0** |
| Authorized By: | Date: Dept: Pharmacy |
| Written By: Patty Heinz | Date: 10/01/2021 |
| Reviewed By: Basil Raad | Date: |
| Date Effective: | |

## 1.0 PURPOSE

1.1 Primera Professional Pharmacy shall require job orientation training for all compounding personnel to ensure that all personnel understand their responsibilities with regard to compounding.

## 2.0 SCOPE

2.1 This procedure applies to all compounding personnel at Primera Professional Pharmacy.

## 3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure or document that another staff member has been designated to complete this task.

## 4.0 REFERENCES

4.1 SOP 1.010 "Policies and Procedures"

4.2 SPO 2.030 "Sterile Compounding Personnel Qualification"

4.3 SOP 2.040 "Non-Sterile Compounding Personnel Qualification"

## 5.0 DEFINITIONS

5.1 N/A

## 6.0 FREQUENCY

6.1 Commencement of employment

6.2 Upon assignment to another position or compounding responsibility

## 7.0 EQUIPMENT & SUPPLIES

7.1 N/A

## 8.0 GENERAL INFORMATION

8.1 All training must be documented and placed in the employee's portfolio.

8.2 Employee portfolio should be updated at least every six months.

8.3 The Pharmacist-in-charge must be qualified and capable of training appropriate staff in the implementation of new or revised SOPs (refer to SOP 1.010, "Policies and Procedures").

## 9.0 PROCEDURE

9.1 All personnel shall complete the job orientation-training program.

9.2 The orientation period shall be used to evaluate the new employee's capability of fulfilling the responsibilities of the position.

9.3 A Job Description (Attachment 1, Attachment 2, or Attachment 3) shall be made available to all compounding personnel. The Job Description will detail job activities, responsibilities, qualifications and requirements for the position.

9.3.1 The employee must read and understand the job description and must sign the job description to acknowledge comprehension.

9.3.2 A member of management must also sign the job description.

9.4 Personnel shall complete the Orientation Checklist (Attachment 4, Attachment 5, or Attachment 6) before assuming all responsibilities of the position. The Orientation Checklist should include, but not be limited to, the following items:

9.4.1 Introduction to management and compounding laboratory staff

9.4.2 Tour of facility

9.4.3 Safety training

9.4.4 USP training

9.4.5 Good Documentation training

9.4.6 Investigation of Method Deviation – OOS

9.4.7 Orientation to designated compounding area and compounding equipment

9.4.8 Review the goals of the compounding laboratory

9.4.9 Daily job responsibilities

9.4.10 Review of Policies and Procedures

9.4.11 Pharmacy practice

9.4.12 Formulation preparation

9.4.13 Quality Assurance/Quality Control

9.4.14 Narcotics and controlled substances

9.5 Upon completion of sterile compounding training, the Personnel Training Verification form (SOP 2.030, Attachment 1) shall be filled out and placed in the employee's portfolio.

9.6 Upon completion of non-sterile compounding training, the Personnel Training Verification form (SOP 2.040, Attachment 1) shall be filled out and placed in the employee's portfolio.

9.7 A personnel portfolio shall be maintained for all compounding personnel. The portfolio shall contain, but not be limited to, the following items:

9.7.1 Resume

9.7.2 Compounding training certificates or appropriate documentation of hours earned (if applicable)

9.7.3 Continuing education certificates or appropriate documentation of hours earned (if applicable)

9.7.4 Appropriate Orientation Checklist

9.7.5 Appropriate Training Verification form

9.7.6 Validation of personnel

9.7.7 Incident reports or complaints specific to a compounder (if applicable)

9.7.8 Employee performance evaluation reports (if applicable)

9.8 Primera Professional Pharmacy shall keep all items in personnel portfolios confidential.

## 10.0 ATTACHMENTS

10.1 Attachment 1 – Job Description – Pharmacist-In-Charge

10.2 Attachment 2 – Job Description – Compounding Pharmacist

| TITLE: COMPOUNDING PERSONNEL ORIENTATION PROGRAM | |
|---|---|
| SOP NUMBER: 2.020 | VERSION NUMBER: 1.0 |
| Date Effective: | |

10.3 Attachment 3 – Job Description – Compounding Support Personnel

10.4 Attachment 4 – Orientation Checklist – Pharmacist-In-Charge

10.5 Attachment 5 – Orientation Checklist – Compounding Pharmacist

10.6 Attachment 6 – Orientation Checklist – Compounding Support Personnel

10.7 Attachment 7 – Personnel Portfolio

## 11.0 HISTORY

| Version Number | Date Effective | Description of Change | Change Request Number |
|---|---|---|---|
| 1.0 | | New SOP. | |

Remainder of this page intentionally left blank.

# JOB DESCRIPTION – PHARMACIST-IN-CHARGE

Please review the following job description for the position of Pharmacist-In-Charge. When you have thoroughly reviewed the responsibilities and understand and accept these responsibilities, please sign and print your name and the date at the bottom of the form. Any questions regarding the responsibilities of this position shall be addressed and resolved before signing.

**General description of the job:**

_____

_____

_____

_____

**Job activities and responsibilities:**

_____

_____

_____

_____

**Minimum qualifications:**

_____

_____

_____

_____

**Physical requirements:**

_____

_____

_____

_____

**Supervisor:**

_____

**Appearance:**

_____

_____

**Team member signature:** _____ **Date:** _____

**Printed name:** _____

**Supervisor:** _____ **Date:** _____

# JOB DESCRIPTION – COMPOUNDING PHARMACIST

Please review the following job description for the position of Compounding Pharmacist. When you have thoroughly reviewed the responsibilities and understand and accept these responsibilities, please sign and print your name and the date at the bottom of the form. Any questions regarding the responsibilities of this position shall be addressed and resolved before signing.

**General description of the job:**

_____

_____

_____

_____

**Job activities and responsibilities:**

_____

_____

_____

_____

**Minimum qualifications:**

_____

_____

_____

_____

**Physical requirements:**

_____

_____

_____

_____

**Supervisor:**

_____

**Appearance:**

_____

_____

**Team member signature:** _____ **Date:** _____

**Printed name:** _____

**Pharmacist-In-Charge:** _____ **Date:** _____

# JOB DESCRIPTION – COMPOUNDING SUPPORT PERSONNEL

Please review the following job description for the position of Compounding Support Personnel. When you have thoroughly reviewed the responsibilities and understand and accept these responsibilities, please sign and print your name and the date at the bottom of the form. Any questions regarding the responsibilities of this position shall be addressed and resolved before signing.

**General description of the job:**

_____
_____
_____
_____

**Job activities and responsibilities:**

_____
_____
_____
_____

**Minimum qualifications:**

_____
_____
_____
_____

**Physical requirements:**

_____
_____
_____
_____

**Supervisor:**

_____

**Appearance:**

_____
_____

**Team member signature:** _____ **Date:** _____

**Printed name:** _____

**Pharmacist-In-Charge:** _____ **Date:** _____

# Pharmacist-in-Charge/ Sterile & Non-Sterile Compounding Pharmacist

**Pharmacists in Charge Responsibilities:**

- Manage our sterile and non-sterile compounding pharmacy location.
- Responsible for all operational aspects of the sterile and non-sterile compounding lab including, but not limited to, Regulatory, Departmental Policy, Quality Assurance, Workflow Efficiency, Staff Supervision, Fiscal Responsibility, and Customer Service. Ensure regulatory compliance for all areas of responsibility.
- Responsible to keep and maintain accurate records and monitor inventory levels in accordance with USP 795/797/800, State Board of Pharmacy regulations, and company policies and procedures.
- Serves as the PIC of the Compounding Lab and personifies the Company's organizational culture by role modeling the company mission, vision and values while providing great leadership.
- Responsible for leadership and operations in the pharmacy while providing industry expertise, insight, and excellent customer service. Ability to lead, motivate and coach other members.
- Directs recruitment, training, development, and evaluation of staff.
- Accountable for meeting budgetary and operational targets.
- Collaborates with Leadership team to develop annual objectives including goals and strategies for department. Creates and monitors infrastructure, systems, processes, and standards to achieve desired results.
- Ensure the presence of an on-going quality improvement program and champions the continuous improvement process for all areas within scope and span of control.
- Directs recruitment, training, development, and evaluation of staff.
- Pharmacist-In-Charge (PIC) responsibilities as prescribed by State regulations.
- Performs other duties as assigned.

**Pharmacists Primary Responsibilities**

- Desire for growth and to play a key role in an exciting independent compounding pharmacy which is committed to exceeding customer expectations, providing the highest quality compounds.
- Knowledge of rules and regulations that govern the practice of pharmacy compounding, knowledge of USP regulations and familiarity with FDA guidance for compounding. Ensure regulatory compliance for all areas of responsibility.
- Compound Sterile and Non-sterile pharmaceutical preparations, including but not limited to the compounding of topical medications and ophthalmic preparations
- Compound medications, fill and label prescriptions, and package medications - in other words, full-service compounding from chemicals to packaging.
- Provide leadership for operational effectiveness, and laboratory staff management. Actively participates in meeting budgetary and operational targets.
- Participates in training, development, and evaluation of staff.
- Collaborates with PIC to develop annual objectives including goals and strategies for department. Creates and monitors infrastructure, systems, processes, and standards to achieve desired results.
- Direct purchasing, storage, distribution, and charge/crediting of drug products. Ensures medication systems incorporate continuous improvement methodologies to operate effectively across the entire continuum of care.
- Counsel clients on different medications, needs, usages, and instructions.
- Keep accurate records and monitor inventory levels in accordance with USP 795/797/800, State Board of Pharmacy regulations, and company policies and procedures.
- Take prescriptions over the phone and by electronic means and enter orders into our proprietary workflow system.
- Develop and maintain positive relationships with providers, patients, and staff.
- Monitor and respond to prescriber and client requests.

**Qualifications**

- Doctorate or BS in Pharmacy
- Registered Pharmacist (Texas) in good standing with the Texas State Board of Pharmacy
- Currently licensed as non-resident pharmacist in other states, or has the ability to obtain non-resident pharmacist licenses as needed
- Sterile IV Certified with Sterile Compounding experience: 1 year preferred

- Non-Sterile Compounding experience: 1 year preferred
- Managerial and Leadership experience: 1 year preferred

**Physical Requirements:**

- Ability to stand for extended time (preferred 8 hours)
- Able to lift up to 30 lbs.

**Supervisor:**

- Reports directly to the President of Pharmacy

**Appearance:**

- Clean, well groomed
- Daily dress code will be black scrubs.

**Team member signature:** _____ **Date:** _____

**Printed name:** _____

**Supervisor:** _____ **Date:** _____

# Sterile & Non-Sterile Compounding Pharmacist

**Pharmacists Primary Responsibilities**

- Pharmacist responsibilities as prescribed by State regulations.
- Desire for growth and to play a key role in an exciting independent compounding pharmacy which is committed to exceeding customer expectations, providing the highest quality compounds.
- Knowledge of rules and regulations that govern the practice of pharmacy compounding, knowledge of USP regulations and familiarity with FDA guidance for compounding. Ensure regulatory compliance for all areas of responsibility.
- Ensure the presence of an on-going quality improvement program and champions the continuous improvement process for all areas within scope and span of control.
- Compound Sterile and Non-sterile pharmaceutical preparations, including but not limited to the compounding of topical medications and ophthalmic preparations
- Compound medications, fill and label prescriptions, and package medications - in other words, full-service compounding from chemicals to packaging.
- Provide leadership for operational effectiveness, and laboratory staff management while providing industry expertise, insight, and excellent customer service. Ability to lead, motivate and coach other members.
- Participates in training, development, and evaluation of staff.
- Collaborates with PIC to develop annual objectives including goals and strategies for department. Creates and monitors infrastructure, systems, processes, and standards to achieve desired results. Actively participates in meeting budgetary and operational targets.
- Direct purchasing, storage, distribution, and charge/crediting of drug products. Ensures medication systems incorporate continuous improvement methodologies to operate effectively across the entire continuum of care.
- Counsel clients on different medications, needs, usages, and instructions.
- Keep accurate records and monitor inventory levels in accordance with USP 795/797/800, State Board of Pharmacy regulations, and company policies and procedures.
- Take prescriptions over the phone and by electronic means and enter orders into our proprietary workflow system.
- Develop and maintain positive relationships with providers, patients, and staff.
- Monitor and respond to prescriber and client requests.
- Performs other duties as assigned.

**Qualifications**

- Doctorate or BS in Pharmacy
- Registered Pharmacist (Texas) in good standing with the Texas State Board of Pharmacy
- Currently licensed as non-resident pharmacist in other states, or has the ability to obtain non-resident pharmacist licenses as needed
- Sterile IV Certified with Sterile Compounding experience: 1 year preferred
- Non-Sterile Compounding experience: 1 year preferred
- Managerial and Leadership experience: 1 year preferred

**Physical Requirements:**

- Ability to stand for extended time (preferred 8 hours)
- Able to lift up to 30 lbs.

**Supervisor:**

- Reports directly to the Pharmacist in Charge

**Appearance:**

- Clean, well groomed
- Daily dress code will be black scrubs.

**Team member signature:** _____ **Date:** _____

**Printed name:** _____

**Supervisor:** _____ **Date:** _____

# Sterile Certified Pharmacy Technician

**General Responsibilities & Duties:**

- Compounding of Sterile and non-sterile products
- Knowledge of USP 797
- Sterile product quality testing and quality control
- Maintain compliance with Pharmacy Standard Operating Procedures and USP
- Excellent telephone communication with patients and prescribing office staff
- Maintain drug inventory utilizing wholesaler ordering and restocking of medications daily and as needed
- Process OTC orders, fill prescriptions, and complete all required documentation
- Technical and practical understanding of pharmacy's standard operating procedures
- Maintain pharmacy records and filing
- Process focused with strong attention to detail, accuracy, and sound judgment

**Candidate Requirements:**

- Sterile Certified Pharmacy Technician
- Licensed with Texas State Board of Pharmacy and in good standing
- Experience in compounding
- Open and flexible availability
- Must be able to multi-task
- Professional, outgoing, friendly, organized
- Reliable, ready to learn and trustworthy
- Good interpersonal skills and communication skills with customer-service focus
- Able to work well with others in a team-oriented environment
- Appearance should reflect positively on the pharmacy
- Able to lift up to 30lbs
- Must have reliable transportation
- Must be able to pass criminal background check and drug testing

**Required experience:**

- Two years of sterile compounding experience.
- Prior experience in a busy pharmacy with multitasking ability.

**Required education and Certifications:**

- High school diploma or higher.
- Current PTCB and TSBP Registration.

**Supervisor:**

- The pharmacist in charge

**Appearance:**

- Clean and well groomed
- Daily dress will be black scrubs

**Team member signature:** _____ **Date:** _____

**Printed name:** _____

**Pharmacist-In-Charge:** _____ **Date:** _____

# Non-Sterile Certified Pharmacy Technician

**General Responsibilities & Duties:**

- Compounding of Sterile and non-sterile products
- Knowledge of USP 795
- Sterile product quality testing and quality control
- Maintain compliance with Pharmacy Standard Operating Procedures and USP
- Excellent telephone communication with patients and prescribing office staff
- Maintain drug inventory utilizing wholesaler ordering and restocking of medications daily and as needed
- Process OTC orders, fill prescriptions, and complete all required documentation
- Technical and practical understanding of pharmacy's standard operating procedures
- Maintain pharmacy records and filing
- Process focused with strong attention to detail, accuracy, and sound judgment

**Candidate Requirements:**

- Certified Pharmacy Technician
- Licensed with Texas State Board of Pharmacy and in good standing
- Experience in compounding
- Open and flexible availability
- Must be able to multi-task
- Professional, outgoing, friendly, organized
- Reliable, ready to learn and trustworthy
- Good interpersonal skills and communication skills with customer-service focus
- Able to work well with others in a team-oriented environment
- Appearance should reflect positively on the pharmacy
- Able to lift up to 30lbs
- Must have reliable transportation
- Must be able to pass criminal background check and drug testing

**Required experience:**

- Two years of non-sterile compounding experience.
- Prior experience in a busy pharmacy with multitasking ability.

**Required education and Certifications:**

- High school diploma or higher.
- Current PTCB and TSBP Registration.

**Supervisor:**

- The pharmacist in charge

**Appearance:**

- Clean and well groomed
- Daily dress will be black scrubs

**Team member signature:** _____ **Date:** _____

**Printed name:** _____

**Pharmacist-In-Charge:** _____ **Date:** _____

# ORIENTATION CHECKLIST – PHARMACIST-IN-CHARGE

The Pharmacist-In-Charge shall be oriented to the pharmacy and the responsibilities and tasks of the position.

| Date | Department/ Procedures Reviewed | Materials/References Used | Initials of Employee | Initials of Pharmacist-In-Charge |
|---|---|---|---|---|
| | Intro to management and compounding staff | | | |
| | Tour of facility | | | |
| | Safety training | | | |
| | USP training | | | |
| | SOPs: Review<br>9.020 Good Documentation<br>1.030 Deviations OOS | | | |
| | Orientation of compounding areas and compounding equipment | | | |
| | Review of goals for compounding laboratory | | | |
| | Daily job responsibilities | | | |
| | Review of Policies and Procedures | | | |
| | Pharmacy Practice and Workflow | | | |
| | Formulation Preparation | | | |
| | Quality Assurance/Quality Control | | | |
| | Narcotics and Controlled Substances | | | |
| | HIPAA and FWA | | | |
| | | | | |
| | | | | |

**Signature:** _____ **Date:** _____
Pharmacist-In-Charge

**Signature:** _____ **Date:** _____
Supervisor

# ORIENTATION CHECKLIST – COMPOUNDING PHARMACIST

The Compounding Pharmacist shall be oriented to the pharmacy and the responsibilities and tasks of the position.

| Date | Department/ Procedures Reviewed | Materials/References Used | Initials of Employee | Initials of Pharmacist-In-Charge |
|---|---|---|---|---|
| | Intro to management and compounding staff | | | |
| | Tour of facility | | | |
| | Safety training | | | |
| | USP training | | | |
| | SOPs: Review<br>9.020 Good Documentation<br>1.030 Deviations OOS | | | |
| | Orientation of compounding areas and compounding equipment | | | |
| | Review of goals for compounding laboratory | | | |
| | Daily job responsibilities | | | |
| | Review of Policies and Procedures | | | |
| | Pharmacy Practice and Workflow | | | |
| | Formulation Preparation | | | |
| | Quality Assurance/Quality Control | | | |
| | Narcotics and Controlled Substances | | | |
| | HIPAA and FWA | | | |
| | | | | |
| | | | | |

**Signature:** _____ **Date:** _____
Compounding Pharmacist

**Signature:** _____ **Date:** _____
Pharmacist-In-Charge

# ORIENTATION CHECKLIST – COMPOUNDING SUPPORT PESONNEL

The Compounding Support Personnel shall be oriented to the pharmacy and the responsibilities and tasks of the position.

| Date | Department/ Procedures Reviewed | Materials/References Used | Initials of Employee | Initials of Pharmacist-In-Charge |
|---|---|---|---|---|
| | Intro to management and compounding staff | | | |
| | Tour of facility | | | |
| | Safety training | | | |
| | USP training | | | |
| | SOPs: Review<br>9.020 Good Documentation<br>1.030 Deviations OOS | | | |
| | Orientation of compounding areas and compounding equipment | | | |
| | Review of goals for compounding laboratory | | | |
| | Daily job responsibilities | | | |
| | Review of Policies and Procedures | | | |
| | Pharmacy Practice and Workflow | | | |
| | Formulation Preparation | | | |
| | Quality Assurance/Quality Control | | | |
| | Narcotics and Controlled Substances | | | |
| | HIPAA and FWA | | | |
| | | | | |
| | | | | |

**Signature:** _____ **Date:** _____
Compounding Support Personnel

**Signature:** _____ **Date:** _____
Pharmacist-In-Charge

# Personnel Portfolio

Employee Full Name _____

Address _____

Phone _____ Cell _____

Preferred Name _____ Date of Birth _____

Position _____ Start Date _____

Hours or Schedule _____

Supervisor _____

Evaluation by _____

**Required documents (please check off)**

( ) Employee Information (this form)

( ) Application (HR maintains)

( ) Resume

( ) Job Description

( ) I9 (HR maintains)

( ) W4 (HR Maintains)

( ) Copy of State License

( ) Screen shot of license verification

( ) Copy of Certifications

( ) HIPAA Acknowledgement

( ) FWA Training

( ) Orientation Checklist

( ) Training Documentation

( ) Incident reports or complaints (if applicable)

( ) Employee performance evaluation reports (if applicable)

| TITLE: CLEANING AND MAINTENANCE OF THE CLEAN ROOM FACILITY | |
|---|---|
| **SOP NUMBER: 3.020** | **VERSION NUMBER: 1.0** |
| Authorized By: | Date: Dept: Pharmacy |
| Written By: Paula Hooper, Pharm.D. | Date: 02/22/2022 |
| Reviewed By: Basil Raad, RPh | Date: |
| Date Effective: | |

## 1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements and documentation for cleaning and maintenance of the clean room facility.

## 2.0 SCOPE

2.1 This procedure applies to the Primera Professional Pharmacy facility under conditions that meet or exceed state and federal guidelines as outlined by the United States Pharmacopeia <797>. This policy must be followed to reduce the amount of particulate matter and airborne microbial contamination.

## 3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge or supervisor shall supervise this procedure and document that all personnel responsible for cleaning and maintenance of the clean room facility shall comply with this procedure.

## 4.0 REFERENCES

4.1 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.2 SOP 1.060 "General Aseptic Technique"

4.3 SOP 3.030 "Environmental Monitoring of the Clean Room Facility"

4.4 SOP 9.100 "Required Garb for Clean Room Facility Access"

## 5.0 DEFINITIONS

5.1 LAFW – Laminar Airflow Workbench

## 6.0 FREQUENCY

6.1 Daily (even if no compounding occurs)

- 6.1.1 Record the temperature, humidity, and pressure differential.
- 6.1.2 Clean and sanitize all in-use hoods.
- 6.1.3 Wipe down all in-use equipment.
- 6.1.4 Clean and sanitize sink.
- 6.1.5 Clean and sanitize door handles.
- 6.1.6 Clean and sanitize all horizontal surfaces and floors.
- 6.1.7 Remove and discard dirty tacky mat sheet.
- 6.1.8 Remove and discard trash.

6.2 Weekly

- 6.2.1 Perform daily requirements listed in section 6.1.
- 6.2.2 Clean and sanitize all supplies stored in the clean room facility.

| TITLE: CLEANING AND MAINTENANCE OF THE CLEAN ROOM FACILITY | | |
|---|---|---|
| **SOP NUMBER: 3.020** | **VERSION NUMBER: 1.0** | |
| Authorized By: | Date: | Dept: Pharmacy |
| Written By: Paula Hooper, Pharm.D. | Date: 02/22/2022 | |
| Reviewed By: Basil Raad | Date: | |
| Date Effective: | | |

6.2.3 Clean and sanitize all walls, ceilings, windows, and doors.

6.3 Monthly

6.3.1 Perform daily requirements listed in section 6.1 and 6.2.

6.3.2 Clean and sanitize all supplies stored in the clean room facility.

6.3.3 Clean and sanitize all items used for storage (shelving, carts, plastic bins, etc.) in the ISO 7 environments.

6.3.4 Clean and sanitize all items used for storage (shelving, carts, plastic bins, cabinets, etc.) in the ISO 8 environments.

6.3.5 Clean and sanitize the drug product refrigerator/freezer.

| TITLE: CLEANING AND MAINTENANCE OF THE CLEAN ROOM FACILITY | | |
|---|---|---|
| **SOP NUMBER: 3.020** | **VERSION NUMBER: 1.0** | |
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| Date Effective: | | |

## 7.0 EQUIPMENT & SUPPLIES

7.1 Mop with disposable cleaning pads labeled for use on the floors of the cleanroom facility only

7.2 Tacky roller mop with tacky roll

7.3 Tacky mat

7.4 Lint-free towels or wipes

7.5 Bleach concentrate or appropriate cleanser (i.e. quaternary compounds)

7.6 70% sterile isopropyl alcohol (IPA)

7.7 Sporicide (Spor-Klenz® or equivalent)

7.8 Waste container liners

7.9 Step stool if needed

7.10 Room thermometer and hygrometer

7.10 Room pressure monitors

## 8.0 GENERAL INFORMATION

8.1 Cleaning Solutions

8.1.1 2% acidified bleach solution – to be prepared as needed (5 day expiration).

8.1.2 Sterile 70% IPA – for use in areas with equipment that may be damaged by the use of bleach. **All IPA designated for use in the clean room facility must be sterile.**

8.1.3 Nova-Clean or Spor-Klenz® – may be used at a dilution of 1:10 for daily cleaning or other equivalent disinfectant.

8.2 Cleaning effectiveness of the clean room is checked by periodic environmental surveys as per SOP 3.030 "Environmental Monitoring of the Clean Room Facility."

8.3 A bleach or undiluted Spor-Klenz® soak is recommended once a month in rooms where 70% IPA is used.

8.4 A minimum contact time of 10 minutes is recommended for maximum disinfection efficacy when using bleach.

8.5 Document the disinfectant in use on the Cleaning and Maintenance of the Clean Room Facility form (Attachment 1).

## 9.0 PROCEDURE

9.1 Personnel must remove all makeup and jewelry prior to entering the clean room facility.

9.2 Personnel must gown appropriately for the areas to be cleaned following the appropriate gowning procedure.

| TITLE: CLEANING AND MAINTENANCE OF THE CLEAN ROOM FACILITY | | |
|---|---|---|
| SOP NUMBER: 3.020 | VERSION NUMBER: 1.0 | |
| Authorized By: | Date: | Dept: Pharmacy |
| Written By: Paula Hooper, Pharm.D. | Date: 02/22/2022 | |
| Reviewed By: Basil Raad | Date: | |
| Date Effective: | | |

9.3 The necessary cleaning materials are dedicated solely to cleaning the clean room facility. These materials shall be stored in the ante room of the clean room facility and shall be kept separate from other cleaning materials.

9.4 Cleaning solutions shall be prepared as needed.

9.4.1 Do not combine disinfectants or use them in concentrations other than those outlined in the SOPs or manufacturers' recommendations.

9.5 Clean with tacky roller mop to remove any particulate material.

9.6 Cleaning shall be performed using a detergent followed by sanitization. A damp, non-shedding material shall be used for cleaning.

9.7 Except for sanitization of the LAFW, cleaning of the sterile compounding area is prohibited during compounding operations.

9.7.1 Ensure all compounding operations are completed and all equipment has been removed from the LAFW prior to sanitization.

9.7.2 The operator must clean and sanitize the exposed work surfaces (counters and walls) of the LAFW immediately before and after each work day and the counter between each batch preparation, every thirty minutes during continuous compounding periods and immediately should a spill occur.

9.8 The order of cleaning within the clean room facility is as follows:

9.8.1 LAFW (ISO 5)

9.8.2 Buffer room (ISO 7)

9.8.3 Anteroom (ISO 8)

9.8.4 Prep room (ISO 8)

9.9 Daily Requirements (when sterile compounding has occurred)

9.9.1 Temperature, humidity and pressure readings shall be taken in all areas of the clean room facility (buffer room and anteroom).

9.9.1.1 The temperature and humidity in the clean room facility can be monitored electronically.

9.9.1.2 The humidity should be maintained in the range of 30%–65%.

9.9.1.3 The temperature shall be maintained between 63°F–77°F (17°C-25°C).

9.9.1.4 The pressure shall be a minimum of 0.02 inches of water.

9.9.1.5 Document results on the Temperature and Humidity Monitoring of the Clean Room Facility form (Attachment 2) or attach printout and date and initial.

9.9.2 Clean and sanitize the LAFW including all equipment.

9.9.3 Clean and sanitize counter tops.

9.9.4 Wipe down equipment and devices.

| TITLE: CLEANING AND MAINTENANCE OF THE CLEAN ROOM FACILITY | |
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| Reviewed By: Basil Raad | Date: |
| Date Effective: | |

9.9.5 Mop the floors starting from a far corner and working toward the center of the room from each sidewall toward the door.

9.9.6 Peel off layer of tacky mat.

9.9.7 Empty all waste receptacles by removing the filled plastic bag. Wipe the receptacle with cleaning solution and then sanitize, let dry and place a clean plastic bag in the receptacle. **Do not remove or relocate receptacles within the clean room facility.**

9.9.8 Allow all rooms and equipment to air dry before sterile compounding resumes.

9.9.9 Document all activities on the Cleaning and Maintenance of the Clean Room Facility form (Attachment 1). If the equipment is not in use, write "N/A" in the appropriate location on the form.

9.10 Weekly Requirements

9.10.1 Perform daily requirements listed in section 9.9.

9.10.2 Clean and sanitize all supplies stored in the clean room facility.

| TITLE: CLEANING AND MAINTENANCE OF THE CLEAN ROOM FACILITY | |
|---|---|
| SOP NUMBER: 3.020 | VERSION NUMBER: 1.0 |
| Date Effective: | |

9.10.3 Clean and sanitize all walls, ceilings, windows, and doors.

9.11 Monthly Requirements

9.11.1 Includes all requirements listed in section 9.9 and 9.10.

9.11.2 Clean and sanitize the ceiling first (when scheduled) beginning at the farthest point from the door and working toward the door.

9.11.3 Clean and sanitize the walls next (when scheduled) beginning with the wall farthest from the door and working toward the door.

9.11.4 Remove all supplies from shelving and carts and clean and sanitize the storage units.

9.11.5 Clean and sanitize the floor last beginning at the far corner and working toward the center of the room from each sidewall toward the door.

9.11.6 Allow all rooms and equipment to air dry before sterile compounding resumes.

9.11.7 Clean and sanitize the drug product refrigerator and freezer.

9.11.8 Document all activities on the Cleaning and Maintenance of the Clean Room Facility form (Attachment 1). If the equipment is not in use, write "N/A" in the appropriate location on the form.

9.12 All cleaning should be performed upon completion of compounding so the clean room facility is always stored cleaned. Cleaning can be performed as often as needed, but the minimum requirement is at the end of the day after compounding.

9.13 The Pharmacist-in-charge or compliance officer shall ensure the completion of tasks on a daily basis and shall review and sign/date Attachment 1 at the end of each month. The form shall be retained in a cleaning/maintenance binder.

## 10.0 ATTACHMENTS

10.1 Attachment 1 – Cleaning and Maintenance of the Clean Room Facility

10.2 Attachment 2 – Temperature and Humidity Monitoring of the Clean Room Facility

## 11.0 HISTORY

| Version Number | Date Effective | Description of Change | Change Request Number |
|---|---|---|---|
| 1.0 | | New SOP. | |

Remainder of this page intentionally left blank.

# CLEANING AND MAINTENANCE OF THE CLEAN ROOM FACILITY

**Month/Year:** _____ **Cleaning Solution:** _____

| Day | Daily | | | | | | | Monthly | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | LAFW Cleaned/Sanitized | Trash Discarded | Waste Receptacle Cleaned/Sanitized | Countertops Cleaned/Sanitized | Equipment Wiped Down | Tacky Mat Refreshed | Floors Mopped | Ceiling Cleaned/Sanitized | Walls Cleaned/Sanitized | Storage Units Cleaned/Sanitized ISO 7 | Equipment Cleaned/Sanitized | Drug Product Refrigerator Cleaned/Sanitized | Drug Product Freezer Cleaned /Sanitized | Storage Units Cleaned/Sanitized ISO 8 |
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**Reviewed By:** _____ **Date:** _____

# TEMPERATURE AND HUMIDITY MONITORING OF THE CLEAN ROOM FACILITY

**Room:**_____

**Month/Year:** _____

| Day | Temperature (°C) | Humidity (%) | Pressure (inches of water) | Initials | Day | Temperature (°C) | Humidity (%) | Pressure (inches of water) | Initials |
|---|---|---|---|---|---|---|---|---|---|
| 1 | | | | | 17 | | | | |
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| 16 | | | | | | | | | |

Humidity Requirement: 30%-65%

Temperature Requirement: 63°F–77°F (17°C-25°C)

Pressure Requirements: >0.02 inches of water (5 Pa)

**Reviewed By:** _____ **Date:** _____

# TEMPERATURE, HUMIDITY, PRESSURE MONITORING OF CLEAN ROOM FACILITY

**Month/Year:** _____ Temperature 63°F *to* 77°F; Humidity ≤ 65%; Pressure >0.02in of water (5 Pa)

| DATE | TIME | Temperature °F | Humidity % | Pressure in | Initials | TIME | Temperature °F | Humidity (%) | Pressure in | Initials |
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**Reviewed By:** _____ **Date:** _____

# Title of SOP: Shipping / Delivery Out of State

Original: Yes _____ No _____ Revision: Yes _____ No _____Revision No._____

## Responsibility:

The pharmacist-in-charge is responsible for this procedure.

## Purpose:

1. To ensure shipping/delivery will occur only to states in which the pharmacy holds a Non-Resident License
2. To ensure that prescriptions are shipped/delivered in a timely manner to the correct patient.
3. To ensure that prescriptions shipped/delivered out of state are handled safely and properly.
4. To define what procedures are used in cases of lost shipments, delivery errors, and delivery delays.

## Equipment/Supplies Required:

- Appropriate packaging supplies (boxes, cooler boxes, insulated mailers, packing tape, packing inserts, scissors)
- Computer with internet access
- Cold packs
- Shipping Log
- Shipping Temperature Test Log
- Label Printer
- Labels for printer supplied by shipper

## Procedure:

### Normal Delivery Protocols and Delivery Times

The pharmacy will only accept out of state prescriptions for states in which the pharmacy holds an active Non-Resident Pharmacy License. The toll free phone number (800-610-2521) will be provided to all patients.

Patients residing outside of Texas will be contacted upon receipt of a new prescription for verification of patient information and establish a patient profile, consent to receive prescription from the pharmacy, and counseling on medication. Patients will be contacted five to seven days prior to refill due, or instructed to contact us five to seven days prior to refill due dates to ensure a

Approved by _____ Date _____

Implemented by _____ Date_____

continuous supply of medications. Patients not consenting to receiving the prescription from the pharmacy will have the prescription transferred as legally allowed to the pharmacy of their choice.

Prescriptions may be shipped via FedEx regular two to three business days, standard overnight, or priority overnight. Out of state patients receiving medical care locally will have the ability to pick up the prescription. Each patient is contacted by the pharmacy team for address verification, counseling from a pharmacist on the medication, and anticipated time of delivery prior to scheduling. A designated area is set up in the pharmacy for packaging and shipping. Each prescription is reviewed and checked by a pharmacist before dispensing or delivery. Each delivery will include:

- HIPAA information and Privacy Practices
- Medication information, patient education materials

**Packaging**

Each medication will be package with the appropriate shipping materials. Picked-up and deliveries containing medications that require refrigeration will be sent standard overnight and will be packed into non-descript cardboard shipping boxes with fitted foam dividers, sealed with tape along with any required paperwork, and frozen cold packs as appropriate. For room temperature medications, frozen cold packs are added in each box when outside temperature reaches 80 $^{O}$ F or above. Contents will not be identified on the outside of package to protect privacy and discourage theft or diversion. Patients will be aware of incoming delivery and advised to contact pharmacy if package is damaged, appears tampered or does not arrive as expected.

**Shipping Temperature Verification**

Shipping temperature maintenance will be verified twice annually with an actual shipping test. A package will be sent standard overnight delivery with a temperature monitoring device to a designated location in the coldest months of the year and the hottest months of the year. The Shipping Temperature Test Log will be completed and sent with the package. Upon arrival the temperature will be validated and the remainder of the Shipping Temperature Test Log will be completed on arrival to ensure package arrives with medication in the desired storage range. If an exception is found, packaging and shipping processes will be reevaluated and revised. Repeat testing will occur with any changes to shipping/packaging processes are made.

**Shipping Tracking and Monitoring**

All FedEx shipments are sent based on the convenience for the patient, regular two to three business days, standard overnight delivered by 8pm the next day, or priority overnight delivered by 10am next day unless the service is not supported for the specific region or patients request a later date. Changes to overnight delivery times will be adjusted depending on the mediation.

Approved by _____ Date _____

Implemented by _____ Date_____

Electronic logs are maintained for all packages shipped via FedEx. Logs include the name of the patient, shipping address, prescriptions numbers in shipment, and tracking numbers. FedE shipping logs are archived weekly and electronically filed. All shipping logs are maintained for two years.

Electronic logs are downloaded daily and reviewed to ensure that all packages are delivered to the recipient in the time frame chosen. Packages delayed or not delivered will be reviewed and responded to within 48 hours.

Packages shipped through FedEx are picked up on Monday through Thursday before 5:00PM, unless the patient requests Saturday delivery.

**Delivery Accuracy**

Every patient will have a delivery ticket that is created during the delivery preparation step. The delivery ticket will include all medications, information and supplies provided to the patient. A daily log for all deliveries and the method of delivery (FedEx) will be noted on the log unless otherwise specified. Anytime an error occurs in the delivery process (wrong patient, wrong address) a complaint will be documented.

## When Medication is Not Available or Delivery is Delayed

Upon receipt of a new prescription if the pharmacy is unable to fill the medication or the medication has to be ordered, the patient will be contacted. For new prescriptions, delivery will be coordinated with the patient to ensure patient can start medication as soon as needed. For immediate need, the pharmacist will transfer the prescription to another pharmacy more convenient to the patient. For prescription refills, the patient will be asked if they have a sufficient supply of medication to last until the medication can be delivered. If the patient does not have a sufficient supply of medication, the prescription will be transferred to another pharmacy more convenient to the patient.

If FedEx notifies the pharmacy due to weather or logistics of a delayed shipment, the patient will be notified as soon as possible of the delay. The patient will be asked if they have a sufficient supply of medication to last until the medication can be delivered. If the patient does not have a sufficient supply of medication, the pharmacist will reship the medication immediately, or transfer the prescription to another pharmacy more convenient to the patient. The pharmacy will re-route the original package to be returned to the pharmacy.

## Prescriptions for Acute Illness

Upon receipt of a prescription for an acute condition, the patient will be contacted and delivery will be coordinated to ensure the patient can start medication as soon as needed. For immediate need, the pharmacist will transfer the prescription to another pharmacy more convenient to the patient. For prescription refills, the patient will be asked if they have a sufficient supply of medication to last

Approved by _____ Date _____

Implemented by _____ Date_____

until the medication can be delivered. If the patient does not have a sufficient supply of medication, the prescription will be transferred to another pharmacy more convenient to the patient.

## When Medication Did Not Arrive As Scheduled

If the pharmacy discovers a delay in delivery or when a patient reports delayed or lost shipment, pharmacy personnel will refer to shipment log to verify shipment information and contact appropriate courier and track the package for the patient. If shipment is further delayed, lost, or incorrect a replacement supply is sent overnight to the patient. A signature authorization is required for the second delivery. The pharmacy will re-route the original package to be returned to the pharmacy. If the patient does not have a sufficient supply of medication, the pharmacist will transfer the prescription to another pharmacy more convenient to the patient. If the patient does not wish to continue to receive the medication from the pharmacy, the pharmacist will have the prescription transferred as legally allowed to the pharmacy of their choice

All SOP's are reviewed at the end of each calendar year and when policy changes are made. Revisions, if deemed necessary, are added as amendments to the original SOP.

Approved by _____ Date _____

Implemented by _____ Date_____

# 8C

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Pharmacy Application

**Non-Refundable $500.00 Fee**

Rev (8/02/2022)

| Facility Location | Application Type (check all applicable) | Pharmacy Type (check all applicable) | Services the Pharmacy will Provide (check all applicable) |
|---|---|---|---|
| ☐ Nevada | ■ New Pharmacy | ■ Retail/Community | ■ Retail/Community |
| ■ Out-of-State | ☐ Ownership Change* | ☐ Hospital (# beds _____) | ■ Non-sterile Compounding |
| | ☐ Location Change * | ☐ Internet | ■ Sterile Compounding |
| | ☐ Name Change* | ☐ Nuclear | ☐ Mail-Order Service |
| | | ☐ Other: | ☐ Off-site Cognitive Services |
| | * If making a change, provide license #: | | ☐ Long Term Care |
| | | | ☐ Hospital |
| | PH_____ | | ☐ Other: |

| Days of Operation | | Ownership Type (check applicable box) |
|---|---|---|
| ■ Monday | ■ Friday | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12) |
| ■ Tuesday | ■ Saturday | ☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12) |
| ■ Wednesday | ☐ Sunday | ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12) |
| ■ Thursday | ☐ Holidays | ■ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12) |

### Section 1: General Information

Pharmacy Name: Town Total Compounding Center

Physical Address: 415 Crossways Park Drive, Suite B

City: Woodbury State: NY Zip: 11797

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 516-249-7436 Toll Free # (NAC 639.708, NRS 639.23286): 888-676-4886

Fax: 516-249-7437 Contact Email: info@towntotalcompound.com

Website: www.towntotalcompound.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Justin Leung Tan

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23431

**Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)**

| | |
|---|---|
| Name: Justin Leung Tan | NV Pharmacist Registration #: 23431 |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
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| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |

| Section 3: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✔ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction? | | ✔ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry? | | ✔ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✔ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✔ |

**If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.**

**Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)**

| | | |
|---|---|---|
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

**Section 5: Publicly Traded Corporation**

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 6: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 7: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 8: Sole Owner**

Owner's Name: Joseph P Navarra

Business Name: Town Total Compounding Centers, LLC

Business Address: 415 Crossways Park Dr, Suite B

City: Woodbury State: NY Zip: 11797

Telephone: 516-249-7436 Email: joseph.navarra@towntotalcompound.com

**Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)**

## Statement of Responsibility

1. I am the Owner (title) for Town Total Compounding Center (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Joseph P Navarra

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

2/22/23

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joseph P Navarra

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

2/22/23

Date

| Board Use Only | Date Received: 3·8·23 | Amount: 500 | CHECK # 5986 |
|---|---|---|---|

**Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY**

Managing Pharmacist Name: Justin Leung Tan Pharmacist Registration #: 23431

Pharmacy Name: Town Total Compounding Center

**Initial each statement below to indicate you have read and agree with the following:**

JLT I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

JLT I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

JLT I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

JLT I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

JLT I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

| Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |
| 2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state? | | ✔ |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? | | ✔ |
| 4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state? | | ✔ |

**If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.**

| Board Administrative Action: | State: | Date: | Case #: |
|---|---|---|---|
| | | | |

| Criminal Action: | State: | Date: | Case #: | County: | Court: |
|---|---|---|---|---|---|
| | | | | | |

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

2/22/23
Date

| Section 12: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)** | ✓ | ✓ | | |
| • **List the top four stockholders and their percent ownership. NRS 639.231(3)** | ✓ | ✓ | | |
| • **List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)** | | ✓ | | |
| • **For General Partnerships, list the name of each partner. NAC 639.214(2)**<br>• **For Limited Partnerships, list the names of (NAC 639.214(3)):**<br>o **All General Partners;**<br>o **All Limited Partners who hold 10% or more of the interest.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** from the Secretary of State's Office where the business is domiciled, dated within the last **6 months.** | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative Form** http://bop.nv.gov/Services/newapps/Business/ must be completed by the Designated Representative. NAC 639.5005. The requirement does not apply to:<br>a. An applicant or a licensee that is a publicly traded corporation;<br>b. An applicant or licensee whose pharmacy is determined by the Board to be located within a large retail store, including, without limitation, a grocery store, variety store or department store under common ownership; or<br>c. An applicant or licenses in which a majority interest of the applicant or licensee is owned by a pharmacist who is:<br>1) License by the Board; and<br>2) A resident of this state. | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** http://bop.nv.gov/Services/newapps/Business/ must be completed by:<br>**a. For Non-publicly traded -** The top 4 shareholder/stockholders.<br>**b. For Partnerships -** All general partners; all limited partners who hold 10% or more of the interest.<br>**c. For Sole Owner** - The owner. | | ✓ | ✓ | ✓ |
| • **Sterile Compounding Questionnaire** must be completed if the pharmacy will provide sterile compounded drugs. Access form at http://bop.nv.gov/Services/newapps/Business/. | ✓ | ✓ | ✓ | ✓ |
| • **Submit a copy of your most recent pharmacy inspection** from the regulatory or licensing authority of the state, territory or Federal agency in which the pharmacy is located. **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2328(2)(f) | ✓ | ✓ | ✓ | ✓ |
| • **Submit a copy of your license, certification, permit or registration issued to your pharmacy** from the regulatory board or licensing authority of the state or territory in which the pharmacy is located. **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2328(2)(a) | ✓ | ✓ | ✓ | ✓ |
| • **License Verification** by the regulatory board or licensing authority of the state or territory in which the pharmacy is located. You may use the License Verification form here: http://bop.nv.gov/Services/newapps/Business/. **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2238(2)(g) | ✓ | ✓ | ✓ | ✓ |
| • **Copy of DEA Registration if handling controlled substances (REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** | ✓ | ✓ | ✓ | ✓ |
| • **Internet Pharmacy Services Certification (REQUIRED FOR PHARMACIES PROVIDING INTERNET PHARMACY SERVICES)** | ✓ | ✓ | ✓ | X |
| • **Transmit Controlled Substance Prescription Data-** Pharmacies dispensing scheduled II-V controlled substance for human consumption shall, not later than the end of the next business day after dispensing a controlled substance, upload to the Nevada Prescription Monitoring Program (PMP) the information described in paragraph (d) of subsection 1 of NRS 453.162. Registration information found at: https://bop.nv.gov/links/PMP/ | ✓ | ✓ | ✓ | ✓ |

**STATE OF NEW YORK**

**DEPARTMENT OF STATE**

**Certificate of Status**

I, ROBERT J. RODRIGUEZ, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

| | |
|---|---|
| **Entity Name:** | TOWN TOTAL COMPOUNDING CENTERS, LLC |
| **DOS ID Number:** | 4067214 |
| **Entity Type:** | DOMESTIC LIMITED LIABILITY COMPANY |
| **Entity Status:** | EXISTING |
| **Date of Initial Filing with DOS:** | 03/14/2011 |
| **Statement Status:** | CURRENT |
| **Statement Due Date:** | 03/31/2023 |

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on February 23, 2023 at 11:40 A.M.

ROBERT J. RODRIGUEZ, Secretary of State

By Brendan C. Hughes
Executive Deputy Secretary of State

Authentication Number: 100003018291 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

### Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler TOWN TOTAL COMPOUNDING CENTER

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 415 CROSSWAYS PARK DRIVE, SUITE B

City WOODBURY State NY Zip 11797

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 516-249-7436 Website WWW.TOWNTOTALCOMPOUND.COM

Licensing Company Email INFO@TOWNTOTALCOMPOUND.COM

### Section 2: Personal Information

First JOSEPH Middle P Last NAVARRA

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 415 CROSSWAYS PARK DR, SUITE B

City WOODBURY State NY Zip 11797

Telephone 516-249-7436 Email JOSEPH.NAVARRA@TOWNTOTALCOMPOUND.COM

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✔ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| ST. JOHNS UNIVERSITY | | 09/1987-05/1992 | |
| **Address** | **City** | **State** | **Zip** |
| 8000 Utopia Pkwy | QUEENS | NY | 11439 |
| **Diploma/Degree obtained, if any** | | | |
| B.S. | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| HAUPPAUGE HIGH SCHOOL | | 09/1983-05/1987 | |
| **Address** | **City** | **State** | **Zip** |
| 500 LINCOLN BLVD | HAUPPAUGE | NY | 11788 |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 10/2008-PRESENT | [redacted]PRIVET CT | SMITHTOWN | NY | 11787 |
| 11/2000-09/2008 | [redacted]E 70TH ST | NEW YORK | NY | 10065 |
| 01/1974-10/2000 | [redacted]HOMESTEAD CIR | HAUPPAUGE | NY | 11788 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| | | | | |
|---|---|---|---|---|
| Business Name: TOWN TOTAL COMPOUNDING CENTER | | | | From - To (MM/YY – MM/YY): 06/2011-PRESENT |
| Business Address: 415 CROSSWAYS PARK DR | | City: WOODBURY | State: NY | Zip: 11797 |
| Phone: 516-249-7436 | Title: OWNER | | | Number of Employed Hours: 60 HOURS PER WEEK |
| Description of Duties: PHARMACIST | | | | |

| | | | | |
|---|---|---|---|---|
| Business Name: TOWN TOTAL HEALTH | | | | From - To (MM/YY – MM/YY): 10/1994-05/2011 |
| Business Address: 6 E 30TH ST | | City: NEW YORK | State: NY | Zip: 10016 |
| Phone: 212-213-5570 | Title: SUPERVISING PHARMACIST | | | Number of Employed Hours: 60 HOURS PER WEEK |
| Description of Duties: PHARMACIST | | | | |

| | | | | |
|---|---|---|---|---|
| Business Name | | | | From - To (MM/YY – MM/YY) |
| Business Address | | City | State | Zip |
| Phone | Title | | | Number of Employed Hours |
| Description of Duties | | | | |

| | | | | |
|---|---|---|---|---|
| Business Name | | | | From - To (MM/YY – MM/YY) |
| Business Address | | City | State | Zip |
| Phone | Title | | | Number of Employed Hours |
| Description of Duties | | | | |

| | | | | |
|---|---|---|---|---|
| Business Name | | | | From - To (MM/YY – MM/YY) |
| Business Address | | City | State | Zip |
| Phone | Title | | | Number of Employed Hours |
| Description of Duties | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

2/22/23
Date

I, JOSEPH P NAVARRA, **certify that as the designated representative for**

TOWN TOTAL COMPOUNDING CENTER,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. ___ I am at least 21 years of age;
3. ___ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ___ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ___ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ___ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ___ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Joseph Navarra

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/22/23

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Joseph Navarra

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/22/23

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of New York, ss. County of Nassau

I, Joseph Navarra, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

2/22/23

**Date**

Subscribed and Sworn to before me this 22nd day of February 2023

Anne Marie Varrassi

**Notary Public Signature**

Anne-Marie Varrassi
Notary Public, State of New York
No. 01VA4915743
Qualified in Nassau County
Commission Expires Jan 11 2026

(Seal)

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/13/2022)

### Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler TOWN TOTAL COMPOUNDIG CENTER

Pharmacy/MDEG/Wholesaler License # (if applicable) _____

Physical Address 415 CROSSWAYS PARK DRIVE, SUITE B

City WOODBURY State NY Zip 11797

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 516-249-7436 Website WWW.TOWNTOTALCOMPOUND.COM

Licensing Company Email INFO@TOWNTOTALCOMPOUND.COM

### Section 2: Personal Information

First JOSEPH Middle P Last NAVARRA

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 415 CROSSWAYS PARK DR, SUITE B

City WOODBURY State NY Zip 11797

Telephone 516-249-7436 Email JOSEPH.NAVARRA@TOWNTOTALCOMPOUND.COM

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✔ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| ST. JOHNS UNIVERSITY | | 09/1987-05/1992 | |
| **Address** | **City** | **State** | **Zip** |
| 8000 Utopia Pkwy | QUEENS | NY | 11439 |
| Diploma/Degree obtained, if any | | | |
| B.S. | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| HAUPPAUGE HIGH SCHOOL | | | |
| **Address** | **City** | **State** | **Zip** |
| 500 LINCOLN BLVD | HAUPPAUGE | NY | 11788 |
| Diploma/Degree obtained, if any | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 10/2008-PRESENT | [redacted]PRIVET CT | SMITHTOWN | NY | 11787 |
| 11/2000-09/2008 | [redacted]E 70TH ST | NEW YORK | NY | 10065 |
| 01/1974-10/2000 | [redacted]HOMESTEAD CIR | HAUPPAUGE | NY | 11788 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| TOWN TOTAL COMPOUNDING CENTER | | | 06/2011-PRESENT |
| **Business Address** | **City** | **State** | **Zip** |
| 415 CROSSWAYS PARK DR, SUITE B | WOODBURY | NY | 11797 |
| **Phone** | **Title** | | |
| 516-249-7436 | OWNER | | |
| **Description of Duties** | | | |
| PHARMACIST | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| TOWN TOTAL HEALTH | | | 10/1994-05/2011 |
| **Business Address** | **City** | **State** | **Zip** |
| 6 E 32ND ST | NEW YORK | NY | 10016 |
| **Phone** | **Title** | | |
| 212-213-5570 | SUPERVISING PHARMACIST | | |
| **Description of Duties** | | | |
| PHAMACIST | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |
| | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

2/22/23
Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

JOSEPH NAVARRA

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/22/23

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of New York, ss. County of Nassau

I, Joseph Navarra, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

2/23/22

**Date**

Subscribed and Sworn to before me this 22nd day of February 2023

Anne Marie Varrassi

**Notary Public Signature**

Anne-Marie Varrassi
Notary Public, State of New York
No. 01VA4915743
Qualified In Nassau County
Commission Expires Jan 11 2026

**(Seal)**

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

### Section 1: General Information

Pharmacy Name: TOWN TOTAL COMPOUNDING CENTER

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 415 CROSSWAYS PARK DRIVE, SUITE B

City: WOODBURY State: NY Zip: 11797

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 516-249-7436 Toll Free # (NAC 639.708, NRS 639.23286): 888-676-4884

Fax: 516-249-7437 Contact Email: INFO@TOWNTOTALCOMPOUND.OM

Website: WWW.TOWNTOTALCOMPOUND.COM

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): JUSTIN LEUNG TAN

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23431

Name of Person with direct knowledge of compounding procedures: JUSTIN LEUNG TAN

Email of Person with direct knowledge of compounding procedures: JUSTIN.L@TOWNTOTALCOMPOUND.COM

Telephone of Person with direct knowledge of compounding procedures: 516-249-7436

**Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)**

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☑ Low ☑ Medium ☐ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ☑ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
Allergenic extracts

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ☑ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:

6. What laboratory performs this additional testing?
Name: EAGLE ANALYTICAL
Address: 11111 S Wilcrest Dr S1000
City: , Houston State: TX Zip: 77099
Telephone: (800) 745-8916

7. What is your procedure for visual inspection of compounded sterile products?
As the preparation of each container is finished, and before labeling, the finished product will be inspected by holding the container against a black background and a white background to inspect for foreign materials including:

a) Precipitatesb) Undissolved particlesc) Small rubber coresd) Crystalse) Any other foreign materials

Products suspected of being contaminated will not be dispensed for patient use. If any traces are found, the container must be discarded.Visually inspect the container for leaks. If leaks are detected, the container must be discarded.

8. How often do you perform glove fingertip and medial fill testing?
Glove fingertip testing is done monthly and media fill tests are done every 6 months.

9. What is your policy if an employee fails a glove fingertip or media-fill test?
If a failure occurs, re-training will be done and then employee must pass 3 finger tip tests and one media fill test.

10. Describe your initial and annual training program for all personnel performing sterile compounding:
There is once annual training and bi-annual training. Intial training encopasses both.
Annual Training:
ONCE ANNUALLY
Read SOP Binder Pass SOP Quiz Review & Sign Orientation Packet Review & Sign Hazardous Drug Liability Form License/Certification Verification (if applicable)
EVERY 6 MONTHS
Read Aseptic Technique Competency Training Guide Pass Observational Hand Hygiene and Garbing Competency Evaluation Pass Observational Aseptic Technique Competency Evaluation Complete Gloved Fingertip Sampling Complete CSP High-Risk Media Fill Challenge Complete Assessing Cleaning and Disinfection Procedure <797> Written Testing Pass Donning/Doffing Sterile gloves

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
We use sterile Peridox-RTU, PreEmpt-RTU,and Sterile 70% isopropyl Alcohol

Hoods are cleaned at the start of everyday, between compounds and at the end of the day,or if anything spills.
Hoods, counters, pass thrus and floors are cleaned on a daily basis.
Ceilings, walls, storage, floors are cleaned on a monthly basis from the cleanest area to the dirtiest. Cleaning equiptment are dedicated to the clean room suite and the mop heads are all disposable.
All cleaning activities are documented when they occur and all staff that cleans are trained and the training is documented.

12. Who performs the sterile compounding process at your facility?
Justin Leung Tan, Pharm D

13. Who is responsible and accountable for the sterile compounding process at your facility?
Justin Leung Tan, Pharm D

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
Enter the pertinent patient information (Name, address, Phone number) into the FedEx system. Affix the shipping label onto the appropriate shipping container.Tightly close and ensure that the prescription is spill-proof.Place the prescription in the appropriate shipping container, which may include Styrofoam or other temperature-resistant containers.
Add ice packs if applicable. Seal the shipping container.
At least seasonally, the temperature of packaging will be evaluated by tracking products in various forms that require refrigeration. Results will be recorded on the Temperature Tracking Form, and reviewed by the Quality Assurance Officer.
Results that fall out of range will be corrected, and a Quality Improvement Form will be filled out for the event.

| Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.) | | |
|---|---|---|
| 1. What type of primary engineering controls will you be using in your facility? | | |
| 2. Is your BSC or CACI vented 100% to the outside? | ☐ Yes | ☐ No |
| 3. Do you have a negative pressure buffer room at your facility? | ☐ Yes | ☐ No |
| 4. Will you be compounding with antineoplastic HDs or HD API? | ☐ Yes | ☐ No |
| 5. If yes, are the drugs stored in an externally ventilated, negative pressure room? | ☐ Yes | ☐ No |
| 6. Will you be utilizing a closed system transfer device? | ☐ Yes | ☐ No |
| 7. If yes, list the name of the device: | | |
| 8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers? | | |
| 9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs? | | |

**Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)**

1. List the specific high risk sterile products that your facility compounds:

2. What sterilization methods are utilized at your facility?

3. Does your facility utilize biological indicators? ☑ Yes ☐ No

4. If yes, describe how they are utilized:

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joseph P Navarra. R.Ph., FACA, FAPC

Name of Person who Completed the Form

Owner

Title

Signature (copies or stamps not accepted)

02/22/2023

Date

| Board Use Only | Date Received:_____ Date Approved: _____ Approved By: _____ |
|---|---|

2250

# THE UNIVERSITY OF THE STATE OF NEW YORK
## EDUCATION DEPARTMENT

# NEW YORK STATE BOARD OF PHARMACY

2020-23

SUPERVISING PHARMACIST
JOSEPH P. NAVARRA

THIS IS TO CERTIFY

TOWN TOTAL COMPOUNDING CENTERS, LLC
415 CROSSWAYS PARK DR
SUITE B
WOODBURY, NY 11797

is duly recorded as a

# REGISTERED PHARMACY

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE FIRST DAY OF JUNE, 2020.
THIS CERTIFICATE EXPIRES ON THE THIRTY-FIRST DAY OF MAY, 2023.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER
030816

Kimberly A. Leonard
EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

## TOWN TOTAL COMPOUNDING CENTERS, LLC

X

GENERAL INFO | ENFORCEMENT ACTIONS

| | |
|---|---|
| **Type** | Pharmacy |
| **Legal Name** | TOWN TOTAL COMPOUNDING CENTERS, LLC |
| **Trade Name** | --- |
| **Street Address** | 415 CROSSWAYS PARK DR SUITE B<br>WOODBURY NY 11797 |
| **Registration No** | 030816 |
| **Date First Registered** | June 16, 2011 |
| **Registration Begins** | June 01, 2020 |
| **Registered Through** | May 31, 2023 |
| **Supervisor** | 041710 - NAVARRA JOSEPH P |
| **Establishment Status** | Active |
| **Successor** | NONE |




February 24, 2023 12:15 PM (ET)

https://www.op.nysed.gov/verification-search?pharmacyRegistrationNumber=030816&professionCode=020

## TOWN TOTAL COMPOUNDING CENTERS, LLC

X

GENERAL INFO | ENFORCEMENT ACTIONS

**Registration No:** 030816

No Enforcement Actions Found

February 24, 2023 12:15 PM (ET)

https://www.op.nysed.gov/verification-search?pharmacyRegistrationNumber=030816&professionCode=020

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| FT2648004 | 11-30-2025 | $888 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N,3, 3N,4,5 | RETAIL PHARMACY | 10-03-2022 |

TOWN TOTAL COMPOUNDING CENTERS, LLC
415 CROSSWAYS PARK DR STE B
WOODBURY, NY 117972055

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

**THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.**

**CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE**
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| FT2648004 | 11-30-2025 | $888 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N,3, 3N,4,5 | RETAIL PHARMACY | 10-03-2022 |

TOWN TOTAL COMPOUNDING CENTERS, LLC
415 CROSSWAYS PARK DR STE B
WOODBURY, NY 117972055

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

# Nevada State Board Of Pharmacy

(Licensee mailing address for window envelope)

THIS STUB IS YOUR RECEIPT

Date: 01/20/2023
Amount:
License #: 23431

Justin Leung Tan

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Pharmacist
Effective Date:01/20/2023
Expires:10/31/2023

Justin Leung Tan

License #
23431
Active

IDENTIFICATION ONLY
DOES NOT MEET POSTING REQUIREMENTS

Trim ID Card to fit your wallet

Cut Here

**NEVADA**

**STATE BOARD OF PHARMACY**

**Pharmacist**

Expires: 10/31/2023
STATUS: Active

License Type: Pharmacist
License #: 23431
Effective Date:01/20/2023

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENSED

Justin Leung Tan

**NONTRANSFERABLE**

POST THIS LICENSE PROMINENTLY IN A CONSPICUOUS PLACE

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# National Association of Boards of Pharmacy®
# Verified Pharmacy Program® Inspection Form

| | | | |
|---|---|---|---|
| Pharmacy e-Profile ID: | 824605 | | Inspection Information |
| Legal Business Name: | Town Total Compounding Centers, LLC | Conference Call Date: | 6/2/2021 |
| Doing Business As (DBA): | Town Total Compounding Center | Start Time: 24-hour format (13:00) | 15:30 |
| Address: | 415 Crossways Park Drive, Suite B | End Time: 24-hour format (13:00) | 17:30 |
| City: | Woodbury | Onsite Inspection Date: | 6/3/2021 |
| State: | NY | Start Time: 24-hour format (13:00) | 9:30 |
| Zip Code: | 11797 | End Time: 24-hour format (13:00) | 15:30 |
| Telephone number: | 516 249 7436 | Inspector Name: | Cheryl Rashid |
| Toll free number: | 888-678-4884 | Inspection Performed by (NABP, State, etc): | NABP |
| Fax number: | 516 249 7436 | Observer Name/Affiliation (if applicable): | NA |
| Website: | www.totaltowncompound.com | Observer Name/Affiliation (if applicable): | NA |

| Pharmacy Hours of Operation | Check if 24/7 ☐ | | |
|---|---|---|---|
| | Open | | Closed |
| | Start Time: (24-hour format) | End Time: (24-hour format) | (X) |
| Sunday | | | X |
| Monday | 9:00 | 18:00 | |
| Tuesday | 9:00 | 18:00 | |
| Wednesday | 9:00 | 18:00 | |
| Thursday | 9:00 | 18:00 | |
| Friday | 9:00 | 18:00 | |
| Saturday | | | X |

| Key Pharmacy Personnel | Name | Contact (e-mail) | e-Profile ID |
|---|---|---|---|
| Pharmacist in Charge | Joseph Navarra | joseph.navarra@totaltowncompound.com | 580440 |
| Nonsterile Compounding Supervisor | Joseph Navarra | joseph.navarra@totaltowncompound.com | 580440 |
| Sterile Compounding Supervisor | Joseph Navarra | joseph.navarra@totaltowncompound.com | 580440 |
| Hazardous Compounding Supervisor | Joseph Navarra | joseph.navarra@totaltowncompound.com | 580440 |

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| Personnel Present at Time of Inspection | Name | Title | License or registration available and current (Y/N) |
|---|---|---|---|
| 1 | Justin Wu, Pharm D | Pharmacist | Y |
| 2 | Mary Jeanne Fenn, Pharm D | Pharmacist | Y |
| 3 | Kristin Cole, Pharm D | Pharmacist | Y |
| 4 | Ann Marie Varrassi | Customer Service | N/A |
| 5 | Morgan Murray, CPhT | Certified Technician | Y |
| 6 | Lisa Rosato | Customer Service | N/A |
| 7 | Justin Tan | Intern | Y |
| 8 | Manny Ming Song Gao | Student | N/A |
| 9 | Mack Li | Student | N/A |
| 10 | | | |

If more than 10, list the first 10 below, then list the title and number (eg: 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks, etc) for the additional personnel present.

**Business Licensure Information for State of Residence and Federal (board of pharmacy, state controlled substance, DEA, FDA, etc)**

| License/Registration Agency | Business Name on License/Registration | License Type/Number | Expiration Date |
|---|---|---|---|
| New York State Education Department, Division of Professional Licensing Services | Town Total Compounding Centers | Pharmacy/ 030816 | 5/31/2023 |
| Drug Enforcement Administration/US Department of Justice | Town Total Compounding Centers | Controlled Substance/ FT2648004 | 11/30/2022 |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

Inspector Notes: List states in which Non-Resident licenses are held= AZ, CO, CT, FL, GA, ID, IL, KS, ME, MD, MI, LA, NJ, ND, OH, PA, RI, UT, VT, VA, WA, DC, WI. (WV, TX and NV) pending

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2257

## Attachments
(NO PHI, including prescription numbers)

| Attachment Name | Description |
|---|---|
| Doc_01_NS_21.00_TownTotalCompounding_Woodbury_NY | COA from PCCA |
| Doc_02_NS_21.00_TownTotalCompounding_Woodbury_NY | COA from Medisca |
| Doc_03_NS_21.00_TownTotalCompounding_Woodbury_NY | COA from Fagron |
| Doc_04_NS_21.00_TownTotalCompounding_Woodbury_NY | COA from Spectrum |
| Doc_05_NS_21.00_TownTotalCompounding_Woodbury_NY | COA from Letco |

| | Type(s) of practice<br>Type "X" for all that apply | | Type(s) of practice<br>Type "X" for all that apply |
|---|---|---|---|
| Traditional retail | X | Telepharmacy | |
| Open to the Public | X | Central Fill/Processing/Shared Services | |
| Closed Door | | Specialty Pharmacy | |
| Drive-through window | | Handles Medical Marijuana | |
| Mail/Deliver (in state) | X | Nuclear Pharmacy | |
| Mail/Deliver (out-of-state list below) | X | Manufacturer | |
| Veterinary Pharmacy | | Wholesale Distributor | |
| Investigational Drugs, Clinical Trials/Research | | Provide products for "Office Use" | |
| Institutional | | Outsourcing Facility | |
| Long-Term Care | | Nonsterile Compounding | X |
| HMO/PBM only | | Nonsterile Hazardous Drug Compounding | X |
| Internet Pharmacy (New Rx) | | Sterile Compounding | X |
| Internet Pharmacy (Refill Rx) | | Sterile Hazardous Drug Compounding | X |

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| Facility Size in Square Feet and Number of PECs | | Personnel | |
|---|---|---|---|
| Total Pharmacy size: | 4100 | Total Pharmacists: | 4 |
| Nonsterile Compounding Room size: | 665 | Number of Compounding Pharmacists | 4 |
| Nonsterile Compounding powder hoods number: | 2 | Total Graduate Students or Residents: | 0 |
| Nonsterile Hazardous Drugs (HD) Compounding Room size: | 240 | Total Student Interns: | 2 |
| Nonsterile HD Compounding BSC/CACI hoods number: | 1 powder hood | Total Technicians: | 1 |
| Sterile Compounding Ante Room size: | 140 | Number of Compounding Technicians | 0 |
| Sterile Compounding Clean/Buffer Room size: | 130 | Of technicians, how many are certified? | 1 |
| Sterile Compounding Number LAFW hoods/areas: | 2 | Of technicians, how many are techs-in-training? | 0 |
| Sterile Compounding Number BSC hoods: | 0 | Total Other Licensed Personnel: | 0 |
| Sterile Compounding Number CAI/CACI hoods: | 0 | Total Other Unlicensed Personnel: | 3 |
| Negative Pressure Sterile HD Room size: | 72 | Ratio #tech:#RPh present at time of inspection: | 1:2 |
| Sterile HD Compounding Number of BSC hoods: | 2 | Total Pharmacist Hours Per Week | 180 |
| Sterile HD Compounding Number of CACI hoods: | 1 powder hood | Total Technician Hours Per Week: | 42 |

| Volume Dispensed | | Volume Distributed | |
|---|---|---|---|
| Total Prescriptions Dispensed/day: | 100 | Total Orders Distributed/day: | 0 |
| % Veterinary Prescriptions | 0% | % Veterinary Orders | 0% |
| % Controlled Substance Prescriptions | 10% | % Controlled Substance Orders | 0% |
| % Nonsterile Compounded Prescriptions | 50% | % Nonsterile Compounded Orders | 0% |
| % Sterile Compounded Prescriptions | 50% | % Sterile Compounded Orders | 0% |
| % Hazardous Drugs (HD) Prescriptions | 30% | % Hazardous Drugs (HD) Orders | 0% |

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**Definitions:** DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific, is not labeled with the patient name at the pharmacy.

**States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month):**
Note: If not available, request information be sent to VPP and note that information was requested in grid.

| State | Volume Dispensed | Volume DISTRIBUTED | /day, week, month |
|---|---|---|---|
| AK | | | |
| AL | | | |
| AR | | | |
| AZ | 0 | 0 | month |
| CA | | | |
| CO | 0 | 0 | month |
| CT | 13 | 0 | month |
| DC | 0 | 0 | month |
| DE | | | |
| FL | 60 | 0 | month |
| GA | 9 | 0 | month |
| HI | | | |
| IA | | | |
| ID | 5 | 0 | month |
| IL | 0 | 0 | month |
| IN | | | |
| KS | 3 | 0 | month |
| KY | | | |
| LA | 0 | 0 | month |
| MA | | | |
| MD | 6 | 0 | month |
| ME | | | |
| MI | 0 | 0 | month |
| MN | | | |
| MO | | | |
| MS | | | |
| MT | 0 | 0 | month |

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| **Definitions:** DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific, is not labeled with the patient name at the pharmacy. | | | |
|---|---|---|---|
| **States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month):**<br>**Note: If not available, request information be sent to VPP and note that information was requested in grid.** | | | |
| **State** | **Volume Dispensed** | **Volume DISTRIBUTED** | **/day, week, month** |
| NC | | | |
| ND | 8 | 0 | month |
| NE | | | |
| NH | | | |
| NJ | 28 | 0 | month |
| NM | | | |
| NV | | | |
| NY | 101 | 0 | month |
| OH | 0 | 0 | month |
| OK | | | |
| OR | | | |
| PA | 14 | 0 | month |
| RI | 0 | 0 | month |
| SC | | | |
| SD | | | |
| TN | | | |
| TX | | | |
| UT | 0 | 0 | month |
| VA | 2 | 0 | month |
| VT | 0 | 0 | month |
| WA | 3 | 0 | month |
| WI | 0 | 0 | month |
| WV | | | |
| WY | | | |
| Other: | 0 | 0 | month |

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# National Association of Boards of Pharmacy®
# Verified Pharmacy Program® Inspection Form

## General Pharmacy Inspection

**The information and comments obtained in the Nonsterile Compounding and Sterile Compounding inspections are based on USP Chapters <795> and <797>. An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.**

**Facility Name:** Town Total Compounding Centers, LLC dba Town Total Compounding Center
**e-Profile ID:** 824605
**Inspection Date:** 06/02/2021 - 06/03/2021

| | | Finding | Notes |
|---|---|---|---|
| **General Pharmacy** | | | |
| 1.00 | Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.* | No | Justin Wu, PharmD |
| 2.00 | Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite* | yes | 45 hours |
| 3.00 | Are there any other businesses located at this address? *If yes, note type of business and notes* | Yes | This is an office building with many unaffiliated business. |
| 4.00 | Does the pharmacy have any other websites? *Provide list of other names/URLs* | No | |
| 4.01 | Does the pharmacy hold .pharmacy verification? | No | |
| 5.00 | Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list.* | No | |
| 6.00 | Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)? | No | |
| 7.00 | Are patients able to order or refill prescriptions through the website? *If yes, describe.* | Yes | Refill. |
| 8.00 | Are photographs allowed during the inspection (no PHI)? | No | |
| 9.00 | List of additional personnel interviewed as part of the inspection, including name and title: | | NA |
| **Types of Practice Additional Questions** **If any part of a question is no, enter "No" and explain the observation.** | | | |
| 10.00 | If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.* | No | |
| 11.00 | Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.* | No | |
| 12.00 | Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)? | No | |

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# National Association of Boards of Pharmacy®
# Verified Pharmacy Program® Inspection Form

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| | | Finding | Notes |
|---|---|---|---|
| 13.00 | If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.* | N/A | |
| 14.00 | If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.* | N/A | |
| **General Operations and Licensure** | **If any part of a question is no, enter "No" and explain the observation.** | | |
| 15.00 | Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc.* | Yes | State license in lobby, personnel licenses in office area. |
| 16.00 | Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.* | Yes | Dated 5/1/2017. Original inspection at this address with no noted problems and not inspected since. |
| 17.00 | Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.* | No | No deficiencies noted. |
| 18.00 | Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.* | No | |
| 19.00 | Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.* | No | |
| 20.00 | Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.* | Yes | Exemption for not shipping CII. |
| 21.00 | Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.* | No | |
| 22.00 | Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional info.* | No | |
| 23.00 | Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.* | No | |

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# National Association of Boards of Pharmacy®
# Verified Pharmacy Program® Inspection Form

## General Pharmacy Inspection

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**e-Profile ID:** 824605
**Inspection Date:** 06/02/2021 - 06/03/2021

| | | Finding | Notes |
|---|---|---|---|
| 24.00 | Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant contamination, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.* | Yes | April, 20 2016; FDA was applying cGMP standards to all incidents as was corrected in response from TTCC, no further contact from FDA. |
| 25.00 | Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.* | Yes | ACHC and PCAB - 5/24/19. |
| 26.00 | Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.* | No | |
| 27.00 | Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.* | No | |
| 28.00 | Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?* | Yes | 10 years |
| 28.01 | Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?* | Yes | 10 years |
| 28.02 | Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).* | Yes | Electronically |
| 28.03 | Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).* | Yes | Electronically |
| 28.04 | Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).* | Yes | Electronically |
| 28.05 | If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable? | N/A | |
| 29.00 | Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system in place.* | Yes | In P & P all employees so instructed. |
| | **Personnel**<br>**If any part of a question is no, enter "No" and explain the observation.** | | |
| 30.00 | Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.* | Yes | Posted in office area |
| 31.00 | Is there a process for periodic verification of validity of licenses? *Describe the process.* | Yes | Annually every June and monthly OIG checks |

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# National Association of Boards of Pharmacy®
# Verified Pharmacy Program® Inspection Form

## General Pharmacy Inspection

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**Facility Name:** Town Total Compounding Centers, LLC dba Town Total Compounding Center
**e-Profile ID:** 824605
**Inspection Date:** 06/02/2021 - 06/03/2021

| | | Finding | Notes |
|---|---|---|---|
| 32.00 | If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?* | Yes | Immunizations all current via additional CE |
| 33.00 | Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.* | Yes | State ratio is 4:1, today was 1 tech to 3 pharmacists |
| | **Facility and Security** *If any part of a question is no, enter "No" and explain the observation.* | | |
| 34.00 | Does the pharmacy have a working security/alarm system in place? *If yes, describe.* | Yes | Alarm.com; Supra is monitoring company. |
| 35.00 | Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, detail how controlled substances are secured or stored.* | N/A | |
| 36.00 | Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.* | Yes | Key, deadbolt, PIC stays. |
| 37.00 | Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.* | Yes | |
| 37.01 | Is the working area well lit and free of tripping hazards? *If no, document with photo.* | Yes | |
| 37.02 | Is there a sink with hot and cold running water? | Yes | |
| 37.03 | If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.* | No | Picked up by Approved Storage and Waste- every other Tuesday. |
| 37.04 | Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.* | No | |
| 37.05 | Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.* | Yes | Approved Storage and Waste. |
| 38.00 | Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.* | Yes | Conference room |

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**Inspection Date:** 06/02/2021 - 06/03/2021

| | | Finding | Notes |
|---|---|---|---|
| 39.00 | Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77°F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection.* | Yes | 20.2C. Temperature controlled by Lighthouse Temperature Sensor. |
| 39.01 | Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process.* | Yes | Manual and automatic by Lighthouse - red light blinks on equipment- notifies for need to check product. No one is notified about excursions directly but are able to look back at the record to determine the range out and how long it was out once a red light is seen. |
| 39.02 | Are excursion action plans in place including evaluating excursion effects on drug product integrity? | Yes | Investigated and resolved per product MFG recommendation. |
| 40.00 | Are the refrigerator and freezer restricted to drug products only (no food)? | Yes | |
| 41.00 | Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?* | Yes | USP range (2 C to 8 C), red light flashes on appliance if excursion occurs. No one is notified about excursions directly but are able to look back at the record to determine the range out and how long it was out once a red light is seen. Records are maintained for 10 years. |
| 41.01 | Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.* | Yes | 2 C, 3 C. |
| 42.00 | Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?* | Yes | USP range (-25 C to -10 C), red light flashes on appliance if excursion occurs. No one is notified about excursions directly but are able to look back at the record to determine the range out and how long it was out once a red light is seen. Records are maintained for 10 years. |
| 42.01 | Is the temperature in the freezer within the USP range (between –25° to –10°C or –13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.* | Yes | Noted as -19 C, -17.1 C, -18.2 C. |
| 43.00 | Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.* | Yes | Generator |
| 44.00 | Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.* | Yes | Generator |
| 45.00 | Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised? | Yes | Excursion are investigated and resolved per product MFG recommendation. |
| 46.00 | Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List machines and types.* | Yes | Kirby Lester x2 - one for regular one for hazardous. |
| 46.01 | If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products? | Yes | |

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**Inspection Date:** 06/02/2021 - 06/03/2021

| | | Finding | Notes |
|---|---|---|---|
| | **Product Receipt and Inventory**<br>If any part of a question is no, enter "No" and explain the observation. | | |
| 47.00 | Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe* | Yes | Downloaded approval letter, FDA website. |
| 47.01 | Does the pharmacy purchase all prescription drugs directly from the manufacturer? | No | Lesco, PCCA, Medisca, Spectrum, Fagron. |
| 47.02 | Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information and circumstances leading to the purchase.* | Yes | |
| 47.03 | Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.* | Yes | AmerisourceBergen, McKesson |
| 47.04 | Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?* | Yes | FDA Website and inventory technician reviews 3T data. |
| 47.05 | Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)* | No | |
| 47.06 | Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.* | Yes | FDA Website and inventory technician reviews 3T data. |
| 47.07 | Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.* | Yes | PIC responsibility |
| 47.08 | Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.* | Yes | Direct contact with sales representative. |
| 47.09 | Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details including the drug, circumstances, outcome, and identification of agencies to whom reported.* | No | |
| 47.10 | Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Continue to spot check invoices to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.* | Yes | An inventory technician reviews the 3T data. |

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| | | Finding | Notes |
|---|---|---|---|
| 47.11 | Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting? | Yes | Review lot number and manufacturing date and contact the manufacturer. |
| 48.00 | Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?* | N/A | No CII |
| 49.00 | Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?* | N/A | No CII. |
| 50.00 | Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.* | N/A | |
| 51.00 | Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in? | Yes | |
| 52.00 | Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.* | Yes | |
| 53.00 | Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, identify which products and from whom they are purchased (collect name and license of other entity).* | No | |
| 54.00 | Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).* | Yes | RX Dispense tracks |
| 54.01 | Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.* | Yes | BOP |
| 55.00 | Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)? | N/A | No CII. |
| 56.00 | Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.* | N/A | |
| 57.00 | Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).* | Yes | May 3rd, 2021. Every 2 years. |
| 57.01 | Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)? | Yes | |

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# National Association of Boards of Pharmacy®
# Verified Pharmacy Program® Inspection Form

## General Pharmacy Inspection

**The information and comments obtained in the Nonsterile Compounding and Sterile Compounding inspections are based on USP Chapters <795> and <797>.**
**An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.**

**Facility Name:** Town Total Compounding Centers, LLC dba Town Total Compounding Center
**e-Profile ID:** 824605
**Inspection Date:** 06/02/2021 - 06/03/2021

| | | Finding | Notes |
|---|---|---|---|
| 58.00 | Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook. | No | |
| 58.01 | Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.* | No | |
| 59.00 | Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types.* | No | |
| 59.01 | Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.* | N/A | |
| 60.00 | Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?* | Yes | Quarantine bin checked monthly |
| 60.01 | Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer* | Yes | |
| 60.02 | How often is active-stock examined for drugs past the expiration date? | | Monthly |
| 61.00 | Does the pharmacy prepackage bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?* | No | |
| 62.00 | Does the pharmacy prepack multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?* | No | |
| 63.00 | Does the pharmacy return to stock prescription drugs that were filled but never picked up? | No | |
| 63.01 | If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted? | N/A | |

## Prescription Processing

**If any part of a question is no, enter "No" and explain the observation.**

| | | | |
|---|---|---|---|
| 64.00 | **Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?* | Yes | Customer Service or pharmacist, updated with each refill |
| 64.01 | If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?* | N/A | |

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# National Association of Boards of Pharmacy®
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## General Pharmacy Inspection

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| | | Finding | Notes |
|---|---|---|---|
| 65.00 | **Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.* | Yes | Doctors are well known to staff. |
| 65.01 | Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process* | Yes | Call MD |
| 65.02 | Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe the processes include comparing the physical addresses of the patient and prescriber?* | Yes | MD well known and addresses compared. |
| 65.03 | Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.* | Yes | Both |
| 65.04 | If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations? | Yes | |
| 66.00 | **Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.* | Yes | Pharmacist entered then a second pharmacist would review. |
| 67.00 | **DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?* | Yes | By interview of patient and by computer after RX received and at validation of prescription via employee password. |
| 67.01 | Does the DUR include:<br>• drug-drug interaction (Prescription and OTC),<br>• drug-allergy interaction,<br>• therapeutic duplication,<br>• under- or over-utilization (including clinical abuse/misuse),<br>• disease state or condition contraindication,<br>• incorrect dosage or duration of therapy, and<br>• gender or age related contraindications.<br>*Indicate if there are other parameters routinely included in the DUR.* | Yes | |
| 67.02 | In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe.* | Yes | Micromedex, USPDI, Lexicomp. |
| 67.03 | Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates? | Yes | |

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# National Association of Boards of Pharmacy®
# Verified Pharmacy Program® Inspection Form

## General Pharmacy Inspection

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| | | Finding | Notes |
|---|---|---|---|
| 67.04 | Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe.* | Yes | Electronic automatic. |
| 67.05 | Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.* | Yes | |
| 67.06 | Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability* | Yes | Pharmacist only override via unique password |
| 67.07 | Is the DUR process performed electronically by the computer system? *Identify integrated drug database used.* | Yes | First Data Bank |
| 67.08 | If the DUR is manual, is there a system to document:<br>• How manual DUR is performed<br>• Specific issues that were identified<br>• Pharmacist that considered the identified issues and gave the okay to proceed | Yes | Notes section and MAR |
| 67.09 | If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product distribution database used. If not, list compendia used for performing manual DUR.* | N/A | |
| 68.00 | Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.* | Yes | Scanned bar codes and pictures of all data attached. Pharmacist verifies for accuracy. |
| 69.00 | Are filled prescriptions appropriately labeled? *Describe.* | Yes | Container has affixed computer label and auxiliary labels. |
| 70.00 | **Confidentiality:** Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.* | Yes | Levels of access via PIC per job description. |
| 70.01 | Does the pharmacy destroy PHI including labeled prescription vials? | Yes | |
| 71.00 | **Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport? | Yes | Seasonal thermometer monitoring package shipped to patient with response from patient. |
| 72.00 | **Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.*** | N/A | |
| 72.01 | If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.* | N/A | |

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# National Association of Boards of Pharmacy®
# Verified Pharmacy Program® Inspection Form

## General Pharmacy Inspection

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| | | Finding | Notes |
|---|---|---|---|
| 72.02 | If yes, is that location in a different state than this facility? *If so, explain* | N/A | |
| 72.03 | If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing? | N/A | |
| 73.00 | Off-Site Inventory: Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.* | No | |
| 73.01 | Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?* | N/A | |
| 74.00 | Off-Site Inventory: Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.* | No | |
| 74.01 | If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.* | N/A | |
| 74.02 | Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?* | N/A | |
| | **Patient Counseling and Communication**<br>**If any part of a question is no, enter "No" and explain the observation.** | | |
| 75.00 | Does the pharmacist provide counseling for all <u>new</u> prescriptions picked up at the pharmacy (proactively, no "offer")? | Yes | |
| 75.01 | Is an "offer" to counsel made for all <u>new</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer".* | No | |
| 76.00 | Does the pharmacist provide counseling for all <u>refilled</u> prescriptions picked up at the pharmacy (proactively, no "offer")? | No | |
| 76.01 | Is an "offer" to counsel made for all <u>refilled</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer".* | Yes | Pharmacist, customer service, technician. |
| 77.00 | Does the pharmacist provide counseling for <u>refilled</u> prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")? | Yes | |

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# National Association of Boards of Pharmacy®
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## General Pharmacy Inspection

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| | | Finding | Notes |
|---|---|---|---|
| 77.01 | Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer"* | No | |
| 78.00 | Is patient counseling provided for delivered prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.* | Yes | Printed information, toll-free number. |
| 79.00 | Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.* | Yes | Printed information, toll-free number. |
| 80.00 | Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how.* | Yes | Printed and added to the bag. |
| 81.00 | Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how.* | yes | Printed and added to the bag. |
| 82.00 | Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for Isotretinoin, or Tikosyn).* | No | |
| 83.00 | Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how* | Yes | Part of computer system. |
| 84.00 | Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation).* | Yes | Facebook Messenger, Google Messenger, 888 number. |
| 85.00 | Are processes in place to handle a drug recall? | Yes | Run report in computer, follow advise of the recall |
| 86.00 | Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program? | No | |
| 86.01 | Does the take-back program include controlled substances? | N/A | |
| 86.02 | Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.* | N/A | |

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# National Association of Boards of Pharmacy®
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## General Pharmacy Inspection

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**Facility Name:** Town Total Compounding Centers, LLC dba Town Total Compounding Center
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| | | Finding | Notes |
|---|---|---|---|
| **Quality Assurance/Quality Improvement Program** | **If any part of a question is no, enter "No" and explain the observation.** | | |
| 87.00 | Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program* | Yes | PIC |
| 87.01 | Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.* | Yes | Hard copy in a binder |
| 87.02 | "Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to):<br>1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions;<br>2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse.<br>3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy. | Yes | |
| 87.03 | There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.* | Yes | Binder |
| 88.00 | Documentation of QREs starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation forms are hard copy or electronic.* | Yes | Immediate; hard copy. |
| 88.01 | Documentation includes all the pertinent data about the prescription involved including personnel involved at each step. | Yes | |

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## General Pharmacy Inspection

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| | | Finding | Notes |
|---|---|---|---|
| 88.02 | Documentation includes documenting the type of QRE details and how/who discovered the QRE. | Yes | |
| 88.03 | Documentation includes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time. | Yes | |
| 88.04 | Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient. | yes | |
| 89.00 | QRE data collected is analyzed to assess causes and any contributing factors (root cause). *Tell us who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc).* | Yes | PIC does monthly. |
| 89.01 | The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients. | Yes | |
| 89.02 | For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients. | N/A | |
| 90.00 | Quality meetings are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support. | Yes | monthly |
| 90.01 | The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients. | Yes | |
| 90.02 | Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program. | Yes | |

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## General Pharmacy Inspection

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| | | Finding | Notes |
|---|---|---|---|
| 91.00 | **Reporting: Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization.** *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.* | Yes | APMS and patient safety committee |
| 91.01 | **Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?** | Yes | SOP and MedWatch |
| 91.02 | **Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.** | N/A | |
| 92.00 | **Quality Self-Audits are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.** | Yes | |
| 93.00 | **Consumer Surveys are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.** | Yes | Every June both patient and prescriber. |
| 94.00 | **Patient Complaints are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.** | Yes | |

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# National Association of Boards of Pharmacy®
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## Nonsterile Compounding Inspection

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| | | Finding | Notes |
|---|---|---|---|
| **General Operations and Information** | | | |
| 1.00 | Does the pharmacy dispense nonsterile compounded preparations pursuant to a prescription? | Yes | |
| 1.01 | Are patient profiles complete and DUR performed for each prescription? *View selected files for profile to include allergies, disease states/conditions, other medications taken not dispensed by this pharmacy* | Yes | Customer service records list of other medications and pharmacist enters them. |
| 1.02 | Do the compounded prescriptions produce a significant difference from a commercially available drug that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner? | Yes | |
| 1.03 | Are nonsterile compounded prescriptions picked up at the pharmacy? | Yes | |
| 1.04 | Are nonsterile compounded prescriptions delivered to patients in their homes or residential facilities? | Yes | |
| 1.05 | Are nonsterile compounded prescriptions mailed to patients in their homes or residential facilities? | Yes | |
| 1.06 | Are nonsterile compounded prescriptions delivered to the practitioner for administration to the patient in the office, clinic, or facility? | No | |
| 1.07 | Are nonsterile compounded prescriptions mailed to the practitioner for administration to the patient in the office, clinic, or facility? | No | |
| 2.00 | Does the pharmacy distribute nonsterile compounded preparations? *Not pursuant to a prescription, not labeled by the pharmacy with a patient name.* | No | |
| 2.01 | Does the pharmacy distribute nonsterile compounded preparations to practitioners for office use? | No | |
| 2.02 | Does the pharmacy distribute nonsterile compounded preparations to hospitals, clinics, or surgery centers? | No | |
| 2.03 | Does the pharmacy have a sales force that promotes compounded preparations? *List compounds promoted* | Yes | Hormone suppositories, creams, pain creams. |
| 2.04 | Does the pharmacy distribute non-patient specific compounded preparations for promotional purposes? *List compounds provided* | No | |
| 2.05 | If yes, does the sales force hand-deliver these compounds? *List compounds provided* | N/A | |
| 2.06 | If yes, are any of these controlled substances? *List compounds provided* | N/A | |

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| | | Finding | Notes |
|---|---|---|---|
| 3.00 | Does the pharmacy provide nonsterile compounded preparations to other pharmacies for dispensing? | No | |
| 3.01 | If so, does the pharmacy have central fill/shared services contracts or agreements with these pharmacies for patient specific preparations? *Provide List.* | N/A | |
| 4.00 | Does the pharmacy compound oral preparations (tablets, capsules, liquids, lozenges, etc.)? *Provide List.* | Yes | Capsules (betahistine, low dose naltrexone, 5 aminopyridine), troche (ketamine), suspensions (tacrolimus), |
| 5.00 | Does the pharmacy compound topicals (gels, creams, ointments, inserts, suppositories, patches, sprays including nasal sprays, etc.)? *Provide List.* | Yes | Gels (tetracaine), creams (lidocaine, tetracaine, progesterone, estrogen, testosterone), suppositories (progesterone), lotions, nasal sprays. |
| 6.00 | Does the pharmacy compound vitamin or nutritional supplements? *Provide List.* | Yes | Methylcobalamin and Leucovorin together and separately. |
| 7.00 | Does the pharmacy sell any compounds over-the-counter? *Provide list.* | No | |
| 8.00 | Does the pharmacy compound investigational drugs? *Provide List.* | No | |
| 9.00 | Does the pharmacy only make essential copies of a commercially available drug product on the Drug Shortage List or that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner? *Indicate volume or percent compounded currently.* | Yes | 0% |
| 9.01 | If yes, products are verified as appearing on the Drug Shortage List in effect under 506E of the Federal Act at the time of compounding, distribution, and dispensing. | Yes | |
| 9.02 | If yes, the Drug Shortage List is monitored and when a drug product is no longer on the list, any remaining stock is quarantined and not available for distribution or dispensing. *Note: Per FDA guidance, 503B facilities may continue to distribute for 60 days following drug shortage list removal for existing orders.* | Yes | |
| 10.00 | Does the pharmacy perform compounding identified as simple? *Indicate percentage of simple compounding.* 1. Making a preparation that has a USP compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate beyond-use dates (BUDs). 2. Reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer. *Examples include Captopril Oral Solution, Indomethacin Topical preparations- Gel, and Potassium Bromide Oral Solution (Veterinary).* | Yes | 40% |

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# National Association of Boards of Pharmacy®
# Verified Pharmacy Program® Inspection Form

## Nonsterile Compounding Inspection

**The information and comments obtained in the Nonsterile Compounding and Sterile Compounding inspections are based on USP Chapters <795> and <797>. An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.**

**Facility Name:** Town Total Compounding Centers, LLC dba Town Total Compounding Center
**e-Profile ID:** 824605
**Inspection Date:** 06/02/2021 - 06/03/2021

| | | Finding | Notes |
|---|---|---|---|
| 11.00 | Does the pharmacy perform compounding identified as moderate? *Indicate percentage of moderate compounding.*<br>1. Making a preparation that requires special calculations or procedures (such as calibration of dosage unit mold cavities) to determine quantities of components per preparation or per individualized dosage units.<br>2. Making a preparation for which stability data for that specific formula is not available.<br>*Examples include Morphine Sulfate Suppositories, diphenhydramine hydrochloride troches, and mixing two or more manufactured cream products when the stability of the mixture is not known.* | Yes | 40% |
| 12.00 | Does the pharmacy perform compounding identified as complex? *Indicate percentage of complex compounding.*<br>Making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes.<br>*Examples of possible complex preparation types include transdermal dosage forms, modified-release preparations, and some inserts and suppositories for systemic effects.* | Yes | 20% |
| 13.00 | Does the pharmacy perform compounding with hazardous drugs? *Indicate percentage of compounding with hazardous drugs.*<br>NIOSH list of hazardous drugs including chemotherapy, hormones, etc. | Yes | 30% |
| 13.01 | Is the pharmacy aware of the more stringent requirements of the proposed USP Chapter <800>? | Yes | |
| 14.00 | Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)? *Verify that personnel can access them and are familiar with the format.* | Yes | Attached to drug electronically. |
| 15.00 | Does the pharmacy compound using any controlled substances? *Indicate percentage of controlled substance nonsterile compounding.* | Yes | 10% |
| 16.00 | APIs: Does the pharmacy make any nonsterile compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)? | Yes | |
| 16.01 | Does the pharmacy purchase APIs directly from the manufacturer/repackager? *Indicate the source of APIs.* | Yes | PCCA, Letco, Medisca, Spectrum, Fagron. |
| 16.02 | Does the pharmacy verify that the manufacturer/repackager of the API is an FDA-registered facility? *If so, indicate how verified.* | Yes | FDA website |

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| | | Finding | Notes |
|---|---|---|---|
| 16.03 | Does the pharmacy use active ingredients that are not from an FDA-registered facility? *If so, indicate source.* | No | |
| 16.04 | Does the computer track on-hand quantities of APIs used for compounding? *If not, explain.* | Yes | |
| 17.00 | Does the pharmacy perform any testing in-house (not sent to an outside lab)? *If so, what tests are performed in-house?* | No | |
| 18.00 | Does the pharmacy send samples to an outside lab to perform testing? *If so, provide the name of the lab performing testing for the pharmacy and what testing is performed.* | Yes | Eagle Analytical Lab |
| 19.00 | Does the pharmacy use scales/balances for nonsterile compounding? | Yes | |
| 19.01 | If so, what type of scale/balance is used? *List manufacturer and model number.* | | |
| 19.02 | If the scale/balance is electronic, does the pharmacy use the automatic calibration? *Describe process and indicate frequency.* | Yes | Daily. |
| 19.03 | Describe the pharmacist checks for the measurement of each ingredient | | Drawn into PK software automatically. |
| 20.00 | **Quality Assurance/Quality Improvement: Does the pharmacy continuous quality improvement program include nonsterile compounding measures?**<br>**Note: If the facility indicates "yes", please ask each question below to verify.** | Yes | |
| 20.01 | Does the pharmacy continuous quality improvement program include QREs related to the preparation of compounded products? | Yes | |
| 20.02 | Does the pharmacy continuous quality improvement program include personnel testing and verification? | Yes | |
| 20.03 | Does the pharmacy continuous quality improvement program include equipment calibration, testing, etc? | Yes | |
| 20.04 | Does the pharmacy continuous quality improvement program include end product testing (such as: pH, weight, potency, particulates, consistency, etc.)? | Yes | |
| 20.05 | Does the pharmacy continuous quality improvement program include patient or prescriber reports or complaints regarding nonsterile compounded products? | Yes | |

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**National Association of Boards of Pharmacy®**
**Verified Pharmacy Program® Inspection Form**

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| | | Finding | Notes |
|---|---|---|---|
| 20.06 | Does the facility QA program identify action limits or thresholds and the appropriate follow-up mechanisms when action limits or thresholds are exceeded including a recall system? | Yes | |
| 20.07 | Does the recall system include communication with both the patient and the physician/prescriber regarding the affected nonsterile compounded preparation? | Yes | Patient and doctor. |
| 20.08 | Are QREs involving nonsterile compounded preparations or are recalled by the pharmacy reported to the Board of Pharmacy? | Yes | |
| | **Component Selection and Use** | | |
| | **Total Non-Compliant (Includes Unknowns)** | **0** | |
| 21.00 | **Active Pharmaceutical Ingredients (APIs), bulk drug substances:**<br>All bulk drug substances (APIs) used are:<br>1) Compliant with the standards of an applicable USP or NF monograph, if one exists; or<br>2) A component of an FDA-approved human drug product; or<br>3) On the list of bulk drug substances for use in compounding developed by the FDA and issued through regulation (note: must comply with (1) or (2) above until the FDA list is issued) | Compliant | |
| 21.01 | Certificates of analysis (COAs) obtained for all bulk APIs used for compounding. *Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.* NOTE: The COA for an API should be reviewed upon receipt of the API to verify the quality of the API before using to compound. | Compliant | See attachments: Doc_01_NS_21.00_TownTotalCompounding_Woodbury_NY-<br>Doc_05_NS_21.00_TownTotalCompounding_Woodbury_NY. |
| 21.02 | USP- or NF-grade substances used, if available | Compliant | |
| 21.03 | If compendia quality components are not available, chemically pure, analytical reagent grade or American Chemical Society-certified components are used and are determined to be free from impurities. | Compliant | |
| 21.04 | APIs or other components have labeling indicating use for pharmaceutical compounding or manufacturing. Labels do not indicate "for research purposes only", "not for drug use", or are handwritten labels from other pharmacies. *Photograph and describe if found. Request copies of the invoices for products with questionable labels.* | Compliant | |
| 21.05 | If compounding for both humans and animals, APIs or other components that are labeled for veterinary use only are segregated or marked in such a way to prevent them from being used for human compounding | N/A | |

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| | | Finding | Notes |
|---|---|---|---|
| 21.06 | All substances and components have a complete label including a batch control or lot number, and an expiration date. | Compliant | |
| 21.07 | For APIs without an expiration date assigned by the manufacturer or supplier, the pharmacy assigns a conservative expiration date. The expiration date assigned does not exceed three (3) years for ingredients used for non-sterile compounding and does not exceed one (1) year for ingredients used for sterile compounding. *Note: purity and quality testing may be performed to extend.* | Compliant | |
| 21.08 | All APIs and components received without an expiration date are labeled with the date they were received. | Compliant | |
| 21.09 | If the pharmacy repackages APIs into smaller containers for ease of use, the expiration date assigned is conservative (typically the lesser of one year or the actual expiration from the original container). Product may be tested to extend the expiration date but may not exceed the original package expiration date. | n/a | |
| 21.10 | Bulk component containers are labeled with appropriate OSHA hazard communication labels and hazardous substances are segregated (including hormones). | Compliant | |
| 22.00 | Where water is an ingredient, purified or distilled water is used. | Compliant | Purified. |
| 23.00 | Ingredients used for dietary or nutritional supplements meet USP, Food Chemicals Codex (FCC), or NF standards, or the pharmacy has alternate means to determine if the ingredients meet food-grade quality. | Compliant | |
| 24.00 | Pharmacy confirms that there are no preparations for human use made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons (facility has a copy of the list or other way to determine). | Compliant | |
| 25.00 | When manufactured products are used for compounding, all the other excipients in the product are considered relative to the use, effectiveness, and stability of the compounded preparation to be made. | Compliant | |
| 26.00 | For animal compounding: The compounding meets the same standards as compounding for human patients. | N/A | |
| 26.01 | The pharmacist is knowledgeable or has references regarding the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used. | N/A | |

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## Nonsterile Compounding Inspection

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| | | Finding | Notes |
|---|---|---|---|
| 26.02 | It is determined and documented if the animal is used for food (meat, milk, eggs, etc.) or that the animal is a pet. | N/A | |
| 26.03 | The pharmacist familiar with, or has a reference regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals. | N/A | |
| 26.04 | The facility has a list of drugs and components not allowed when compounding for food-producing animals. | N/A | |
| 26.05 | The pharmacist is familiar with, or has a reference regarding regulations for drug use in performance animals (e.g., race or show horses, racing dogs) | N/A | |
| **Beyond Use Dating (BUD)** | | | |
| | **Total Non-Compliant (Includes Unknowns)** | **0** | |
| 27.00 | BUDs are assigned from the day of preparation. | Compliant | |
| 28.00 | BUDs are assigned based on dispensing in tight, light-resistant containers/overpacks. | Compliant | |
| 29.00 | Extended BUDs are supported by testing data. *View documentation used, preparation must exactly match formulation upon which data was obtained.* | Compliant | |
| 29.01 | Extended BUDs are assigned and the facility has performed its own stability testing. *View records, preparation must exactly match the preparation tested by the facility including concentration of all active ingredients, excipients, etc.* | compliant | |
| 30.00 | BUDs for nonaqueous formulations are not later than the remaining time until the earliest expiration date of any API and not later than six (6) months. | Compliant | |
| 31.00 | BUDs for water-containing oral formulations are not later than 14 days when stored at controlled cold temperatures (refrigerated). | Compliant | |
| 32.00 | BUDs for water-containing topical/dermal and mucosal liquid and semisolid formulations not later than 30 days. | Compliant | |

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## Nonsterile Compounding Inspection

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**Facility Name:** Town Total Compounding Centers, LLC dba Town Total Compounding Center
**e-Profile ID:** 824605
**Inspection Date:** 06/02/2021 - 06/03/2021

| | | Finding | Notes |
|---|---|---|---|
| **Environment** | | | |
| | **Total Non-Compliant (includes Unknowns)** | **0** | |
| 33.00 | The non-sterile compounding area is a controlled environment and separate from the general pharmacy. | Compliant | |
| 34.00 | There sufficient space available for the type and amount of compounding performed and the space is orderly to prevent mix-ups between ingredients, containers, labels, in-process materials, and finished preparations. | Compliant | |
| 35.00 | Only one preparation compounded at a time. | Compliant | |
| 36.00 | Procedures are implemented to prevent cross-contamination, especially when compounding with drugs such as hazardous drugs and known allergens like penicillin that require special precautions. | Compliant | |
| 37.00 | The compounding area is well lit. | Compliant | |
| 38.00 | The pharmacy performs hazardous non-sterile compounding in a ventilated cabinet such as a BSC, CAI, or CACI. *Note: CAI may not be used for hazardous drugs that may volatilize (NIOSH requirement referenced in USP<795>. Note that proposed USP Chapter <800> will change hazardous drug compounding requirements.)* | Compliant | |
| 38.01 | Ventilated cabinets (BSC, CAI, CACI) used for hazardous compounding are certified or tested periodically. | Compliant | Every 6 months. |
| 38.02 | If the hoods or isolators are not located in a closed, controlled room environment, there is documentation from the manufacturer and site testing to verify proper functioning of equipment under dynamic conditions for the safety of personnel. | Compliant | |
| 39.00 | Appropriate protective attire (gowns, gloves, masks, etc.) is available. | Compliant | |
| 39.01 | If hazardous drugs are used, appropriate protective attire is available (gowns, gloves, hair and shoe covers, eye and face protection, etc.). | Compliant | |
| 40.00 | There is a sink in the compounding area with hot and cold potable water, soap or detergent, and air-driers or single-use towels. | Compliant | |
| 41.00 | There is adequate space to wash equipment and utensils including access to water for rinsing. *(Purified water is recommended - not required)* | Compliant | Purified used. |

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## Nonsterile Compounding Inspection

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**Facility Name:** Town Total Compounding Centers, LLC dba Town Total Compounding Center
**e-Profile ID:** 824505
**Inspection Date:** 06/02/2021 - 06/03/2021

| | | Finding | Notes |
|---|---|---|---|
| 42.00 | The temperature of the compounding area is controlled by a thermostat and an air conditioning system is in place. | Compliant | |
| 43.00 | Temperature in the compounding area is maintained to provide controlled room temperature of 20° to 25°C (68° to 77°F), or more restrictive if warranted by specific drug product storage requirements. | Compliant | 20.2 C |
| 43.01 | Temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained. | Compliant | Lighthouse Monitoring. |
| 43.02 | Excursion action plan in place including evaluating excursion effects on drug product integrity. | Compliant | |
| 43.03 | Temperature monitoring is also performed in drug storage areas (if separate from the compounding areas) and maintained within 20° to 25°C (68° to 77°F), or more restrictive if warranted by specific drug product storage requirements. | Compliant | 20 C |
| 43.04 | Temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained. | Compliant | Lighthouse Monitoring. |
| 43.05 | Excursion action plan in place including evaluating excursion effects on drug product integrity. | Compliant | |
| 44.00 | Humidity in the compounding area is maintained to provide humidity in the ranges warranted by specific drug product storage requirements. If drug products require storage in a "dry place", humidity is not to exceed 40%. Generally recommended range is 35-60%. | Compliant | 53.1 RH |
| 44.01 | Humidity monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained. | Compliant | |
| 44.02 | Excursion action plan in place including evaluating excursion effects on drug product integrity. | Compliant | Isolation, separate area, quarantine |
| 44.03 | Humidity monitoring is also performed in drug storage areas (if separate from the compounding areas) to provide humidity in the ranges warranted by specific drug product storage requirements. If drug products require storage in a "dry place", humidity is not to exceed 40%. Generally recommended range is 35-60%. | Compliant | 53.1 RH |
| 44.04 | Humidity monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained. | Compliant | |
| 44.05 | Excursion action plan in place including evaluating excursion effects on drug product integrity. | Compliant | |

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## Nonsterile Compounding Inspection

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**Facility Name:** Town Total Compounding Centers, LLC dba Town Total Compounding Center
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| | | Finding | Notes |
|---|---|---|---|
| 45.00 | The bulk component storage area is adequately arranged and maintained in a clean and sanitary condition. | Compliant | |
| 46.00 | All components, equipment, and containers are stored off the floor, and handled and stored to prevent contamination. | Compliant | |
| 47.00 | All components and packaging containers and closures are properly rotated to use oldest first. | Compliant | |
| 48.00 | Hazardous drugs are appropriately identified and marked, received, handled and stored by appropriately trained personnel. (OSHA regulations and NIOSH Alerts) | Compliant | |
| 49.00 | Trash is disposed of in a safe, sanitary, and timely manner. | Compliant | |
| 49.01 | Hazardous waste is disposed of in a safe, sanitary, and timely manner. | Compliant | |
| **Training** - *Verify records of all compounding personnel (up to 10).* | | | |
| | **Total Non-Compliant (Includes Unknowns)** | **0** | |
| 50.00 | Have all personnel of reproductive capability who handle or compound hazardous drugs or chemicals confirmed in writing that they understand the risks of handling hazardous drugs? Teratogenicity, carcinogenicity, reproductive issues. | Compliant | |
| 51.00 | There is documentation that all personnel that perform compounding are appropriately trained including policies and procedures, documentation, hazardous drug handling, and compounding technique and not allowed to compound or supervise compounding until training is successfully completed. | Compliant | |
| 52.00 | There is documentation that the training process for the preparation of compounds includes demonstration of the compounding procedure first, followed by the trainee performing the procedure under supervision successfully before being allowed to perform compounding. | Compliant | |
| 53.00 | There is documentation that training includes the operation of any equipment that may be used when preparing compounded products. *Documentation includes operation and troubleshooting.* | Compliant | |
| 54.00 | There is documentation available showing employees performing non-sterile compounding are evaluated at least annually. | Compliant | |

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| | | Finding | Notes |
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| 54.01 | If performing hazardous nonsterile compounding, there is documentation available showing employees are evaluated at least annually. | Compliant | |
| 55.00 | If the pharmacy uses relief personnel from outside agencies to perform non-sterile compounding there is documentation that training is verified. | Compliant | |
| **Compounding Equipment** | | | |
| | **Total Non-Compliant (includes Unknowns)** | **0** | |
| 56.00 | Appropriate equipment and utensils are available, clean, and in good working order. *Automated, mechanical, or electronic equipment (including capsule machines, autoclaves, ovens, etc.) are periodically inspected and calibrated.* | Compliant | |
| 57.00 | Scales, balances, or other types of equipment used for measurement shall be routinely inspected, calibrated as necessary (per manufacturer instructions), and checked to ensure proper performance. *Describe procedure used.* | Compliant | Calibrated daily, scales inspected by state sealed and tested yearly. |
| 58.00 | Powder hoods used for nonsterile compounding are certified or tested periodically to ensure proper function. | compliant | |
| 58.01 | Hood filters are checked regularly and replaced when necessary. | Compliant | |
| 59.00 | All equipment is cleaned promptly after each use. *Equipment and utensils washed using potable water with a soap or detergent, and rinsed. Recommended rinsed with purified water.* | Compliant | |
| 60.00 | The pharmacy uses separate equipment and utensils to compound allergenic, cytotoxic, or hazardous products, or has detailed procedures for meticulous cleaning of equipment and utensils immediately after use to prevent cross-contamination or exposure. | Compliant | |
| **Documentation** | | | |
| | **Total Non-Compliant (includes Unknowns)** | **0** | |
| 61.00 | The pharmacy creates a master formulation record the first time before compounding a new preparation | Compliant | |
| 61.01 | Every formulation is evaluated for incompatibilities and the potential for being ineffective or toxic. | Compliant | |
| 61.02 | The master formulation record includes: | | |

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| | | Finding | Notes |
|---|---|---|---|
| 61.03 | Official or assigned name, strength, and dosage form | Compliant | |
| 61.04 | All necessary calculations | Compliant | |
| 61.05 | Description of all ingredients and their quantities | Compliant | |
| 61.06 | Compatibility and stability information including references (when available) | Compliant | |
| 61.07 | Equipment used for the preparation | Compliant | |
| 61.08 | Mixing instructions (order of mixing, temperatures, duration of mixing, and other pertinent factors) | Compliant | |
| 61.09 | Container used and packaging requirements | Compliant | |
| 61.10 | Assigned BUD information | Compliant | |
| 61.11 | Labeling information including the name of and quantity or concentration of each active ingredient | Compliant | |
| 61.12 | Description of the finished preparation | Compliant | |
| 61.13 | Storage requirements | Compliant | |
| 61.14 | Quality control procedures and expected results (e.g. dose measurement of capsule in the dose calibrator). | Compliant | |
| 62.00 | The pharmacy creates a compounding record for each compound prepared | Compliant | Ursodiol Susp 60mg/ml 60 ml seen compounded. |
| 62.01 | The compounding record includes: | | |
| 62.02 | Official or assigned name, strength and dosage of the preparation | Compliant | |
| 62.03 | Master Formulation Record reference | Compliant | |
| 62.04 | Sources, lot numbers, and expiration dates of all components | Compliant | |
| 62.05 | Total quantity or number of dosage units compounded | Compliant | |
| 62.06 | Person compounding the preparation | Compliant | |

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| | | Finding | Notes |
|---|---|---|---|
| 62.07 | Person performing the quality control procedures | Compliant | |
| 62.08 | Person who approved the preparation | Compliant | |
| 62.09 | Date of compounding | Compliant | |
| 62.10 | Assigned internal identification number or prescription number | Compliant | |
| 62.11 | Description of the final preparation | Compliant | |
| 62.12 | Assigned BUD | Compliant | |
| 62.13 | Duplicate label | Compliant | |
| 62.14 | Results of quality control procedures (weight range of filled capsules, pH of aqueous liquids, etc.)? | Compliant | |
| 62.15 | Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver including investigation and recall, if appropriate | Compliant | |

## Compounding Procedures

| | | | |
|---|---|---|---|
| | Total Non-Compliant (Includes Unknowns) | 0 | |
| 63.00 | The Master Formulation Record and the Compounding Record has been reviewed by the compounder to ensure it is error free. | Compliant | |
| 64.00 | Compounding personnel ascertain that ingredients for compounded preparations are of the correct identity and appropriate quality including a unit-by-unit inspection of the components. | Compliant | |
| 65.00 | The containers and closures selected meet USP standards (from container supplier). | Compliant | |
| 66.00 | Container selection determined by physical and chemical properties of the preparation. | Compliant | |

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# National Association of Boards of Pharmacy®
# Verified Pharmacy Program® Inspection Form

## Nonsterile Compounding Inspection

**The information and comments obtained in the Nonsterile Compounding and Sterile Compounding inspections are based on USP Chapters <795> and <797>.**
**An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.**

**Facility Name:** Town Total Compounding Centers, LLC dba Town Total Compounding Center
**e-Profile ID:** 824605
**Inspection Date:** 06/02/2021 - 06/03/2021

| | | Finding | Notes |
|---|---|---|---|
| 67.00 | Compounding personnel maintain good hand hygiene and wear clean and appropriate clothing for the compounding being performed. | Compliant | |
| 68.00 | Personnel don appropriate protective garb when performing compounding. | Compliant | |
| 68.01 | If hazardous compounding, personnel don appropriate protective garb when compounding. | Compliant | Tacrolimus Oral Susp 1mg/ml 135ml seen compounded. |
| 69.00 | Routine compounding procedures for batch preparation completed and verified according to written procedures. Including: *Calculations correct, weighing and measuring performed correctly, order of mixing correct, compounding techniques performed correctly* | Compliant | |
| 70.00 | Procedures for in-process checks followed. *These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists that includes visual inspection of product, and documentation of the compounding accuracy is performed to ensure proper measurement, reconstitution and component usage. Recommended: compounding accuracy checked by a person other than the compounder.* | Compliant | |
| 71.00 | There are no deviations from the master formulation record, unless they are approved and deemed appropriate by a pharmacist and a new master formulation record is created. | Compliant | |
| 72.00 | There is a procedure for cleaning which is followed. *After each preparation, daily tasks, monthly tasks, etc.* | Compliant | |
| 73.00 | Personnel are appropriately garbed for protection when cleaning. | Compliant | |
| 74.00 | Compounding employees are using appropriate techniques. *Inspector to observe compounding procedures, documentation, appropriate garb, cleanliness of compounding area and equipment. Compounding MUST be observed, if compounding is not being performed at the time of survey, mark as "Not Compliant".* | Compliant | Ursodiol Susp 60mg/ml 60 ml observed. |
| 74.01 | If compounding is not being performed at the time of survey, ask that a compounding pharmacist or technician prepare a compound for you to observe the compounding process. *If the pharmacy staff refuses or is unable to perform compounding for you to observe, document on the "Denial of Authorization" form. List individual who signs the Denial of Authorization* | | |

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| | | Finding | Notes |
|---|---|---|---|
| **Finished Preparation Release Checks and Tests** | | | |
| | **Total Non-Compliant (Includes Unknowns)** | **0** | |
| 75.00 | The finished preparation is observed to appear as expected in the master formulation record and documented. | Compliant | |
| 76.00 | As appropriate, the final completed preparation assessed for quality control and is documented, such as weight, mixing, clarity, odor, color, consistency, pH, and strength. | Compliant | |
| 77.00 | There are established written processes that describe test or examinations conducted on the compounded preparation (degree of weight variation in capsules, for example) to ensure uniformity and integrity. | Compliant | |
| 78.00 | Preparations with extended BUDs that are not supported by testing data are sampled and tested for physical, chemical, and microbiological characteristics. | Compliant | |
| 78.01 | If any failed tests or discrepancies are observed, there is an investigation and appropriate corrective actions taken before dispensing to patient | Compliant | No failed tests reported |
| 78.02 | If products being tested are dispensed or distributed before the test results are obtained, there is a recall procedure if the test results indicate an issue. | Compliant | Dispensed but recalled of failed test |
| 79.00 | There are appropriate quality control procedures to monitor the output and to verify the performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations. *Review validation of equipment and personnel performance documentation.* | Compliant | |
| 80.00 | Labels on immediate patient-specific containers include identifiers for the persons preparing the compound and performing the final verification, BUD, an indication that this is a compounded preparation, special requirements for storage, and appropriate packaging and labeling of hazardous materials: | Compliant | |
| 80.01 | Labeling contains generic name and quantity or concentration of each active ingredient. | Compliant | |
| 80.02 | Labeling contains assigned BUD. | Compliant | |
| 80.03 | Labeling contains storage and handling information. | Compliant | |
| 80.04 | If hazardous, labeling contains storage and handling information. | Compliant | |

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| | | Finding | Notes |
|---|---|---|---|
| 80.05 | Labeling contains prescription or control number, whichever is applicable. | Compliant | |
| 81.00 | Batch preparations (in anticipation of prescriptions) are of an appropriate volume and batch products in stock are all within their BUD (not outdated). | Compliant | |
| 82.00 | Labels on batch preparations include the name and quantity of all contents, date and time of preparation (or internal code/lot number indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials. | Compliant | |
| 83.00 | Preparations are stored and secured properly prior to dispensing based upon conditions upon which BUD was assigned. | Compliant | |
| 84.00 | Preparations are examined immediately after preparation AND again immediately prior to dispensing for any signs of instability. | Compliant | |
| **Patient Counseling and Communication** | | | |
| | **Total Non-Compliant (includes Unknowns)** | **0** | |
| 85.00 | Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of products such as fentanyl, hormones and chemotherapy medications? | Compliant | |
| 86.00 | Are the required printed drug information materials (drug information sheets, Patient Package Inserts, MedGuides, etc.) provided for the compounded products? | Compliant | |
| 87.00 | Are patients instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy? | Compliant | |
| 88.00 | Product recalls include documentation that both the patient AND the physician/prescriber of the potentially contaminated compounded product are notified of the potential risk. | Compliant | |

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## Sterile Compounding Inspection

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**Facility Name:** Town Total Compounding Centers, LLC dba Town Total Compounding Center
**e-Profile ID:** 824605
**Inspection Date:** 06/02/2021 - 06/03/2021

| | | Finding | Notes |
|---|---|---|---|
| | Indicate the drug name, dosage or strength, and the size of the sample obtained for testing. *(NA if no sample)* | | NA |
| | Indicate the areas/rooms of the pharmacy entered to perform the inspection. *If the inspector did not fully garb and enter buffer room(s), indicate reason.* | | Fully visualized via windows. |
| | **General Operations Information** | | |
| 1.00 | Does the pharmacy dispense sterile compounded preparations pursuant to a prescription? | Yes | |
| 1.01 | Are patient profiles complete and DUR performed for each prescription? *View selected files for profile to include allergies, disease states/conditions, other medications taken not dispensed by this pharmacy.* | Yes | |
| 1.02 | Are sterile compounded prescriptions picked up at the pharmacy? | Yes | |
| 1.03 | Are sterile compounded prescriptions delivered/mailed to patients in their homes or residential facilities? | Yes | |
| 1.04 | Are sterile compounded prescriptions delivered/mailed to the practitioner for administration to the patient in the office, clinic, or facility? | No | |
| 2.00 | Does the pharmacy distribute sterile compounded preparations? *Not pursuant to a prescription, not labeled by the pharmacy with a patient name.* | No | |
| 2.01 | Does the pharmacy distribute sterile compounded preparations to practitioners for office use? | No | |
| 2.02 | Does the pharmacy distribute sterile compounded preparations to hospitals, clinics, or surgery centers? | No | |
| 2.03 | Is the pharmacy registered with the FDA as an Outsourcing Facility? | No | |
| 2.04 | Does the pharmacy have a sales force that distributes samples containing active ingredients? *List samples provided.* | No | |
| 3.00 | Does the pharmacy provide sterile compounded preparations to other pharmacies for dispensing? | No | |
| 3.01 | If so, does the pharmacy have central fill/shared services contracts or agreements with these pharmacies for patient specific preparations? | N/A | |
| 4.00 | Which of the following sterile compounds are prepared? | | |
| 4.01 | Allergen extracts | Yes | |

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## Sterile Compounding Inspection

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| | | Finding | Notes |
|---|---|---|---|
| 4.02 | Parenteral solutions | Yes | |
| 4.03 | Parenteral *suspensions* | Yes | |
| 4.04 | Preservative-free parenterals | Yes | |
| 4.05 | Ophthalmic preparations | Yes | |
| 4.06 | Oral or nasal *inhalation* preparations (not topical sprays) | Yes | Nasal only |
| 4.07 | Baths and soaks for live organs and tissues | No | |
| 4.08 | Irrigations for wounds and body cavities | Yes | |
| 4.09 | Any other sterile preparations (implants, pellets, etc.). *Provide list.* | No | |
| 5.00 | Does the pharmacy compound investigational drugs? *Provide list.* | No | |
| 6.00 | Does the pharmacy only make essential copies of a commercially available drug product on the Drug Shortage List or that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner? *Indicate name and volume/percent compounded currently.* | Yes | 0% none currently |
| 6.01 | If yes, products are verified as appearing on the Drug Shortage List in effect under 506E of the Federal Act at the time of compounding, distribution, and dispensing. | Yes | |
| 6.02 | If yes, the Drug Shortage List is monitored and when a drug product is no longer on the list, any remaining stock is quarantined and not available for distribution or dispensing. *Note: Per FDA guidance, 503B facilities may continue to distribute for 60 days following drug shortage list removal for existing orders.* | Yes | |
| 7.00 | Does the pharmacy perform low-risk compounding? *Indicate percentage of low risk sterile compounding.* | Yes | 40% |
| 7.01 | Are all low-risk compounds assigned BUDs within USP guidelines (48 hours at controlled room temperature, 14 days refrigerated, 45 days frozen)? | Yes | |
| 7.02 | If low risk, are the compounds located in segregated area are BUD 12 hours or less? | N/A | |
| 7.03 | If extended BUDs are used, list products with Extended BUDs and maximum BUD in notes. | | |
| 7.04 | If extended BUDs are used, is further testing being performed to justify the use of extended BUDs? *List the types of testing performed (potency, sterility, stability, etc).* | N/A | |
| 8.00 | Does the pharmacy perform medium-risk compounding? *Indicate percentage of medium-risk sterile compounding.* | Yes | 40% |

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## Sterile Compounding Inspection

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**Inspection Date:** 06/02/2021 - 06/03/2021

| | | Finding | Notes |
|---|---|---|---|
| 8.01 | Are all medium-risk compounds assigned BUDs within USP guidelines (30 hours at controlled room temperature, 9 days refrigerated, 45 days frozen)? | Yes | Atropine eye drops BUD 60 days, Methylcobalamin/Leucovorin injection BUD 90 days. |
| 8.02 | If extended BUDs are used, list products with Extended BUDs and maximum BUD in notes. | | |
| 8.03 | If extended BUDs are used, is further testing being performed to justify the use of extended BUDs? *List the types of testing performed (potency, sterility, stability, etc).* | Yes | Every batch sterility every other batch stability. |
| 9.00 | Does the pharmacy perform high-risk compounding? *Indicate percentage of high-risk sterile compounding.* | Yes | 20% |
| 9.01 | Are all high-risk compounds assigned BUDs within USP guidelines (24 hours at controlled room temperature, 3 days refrigerated, 45 days frozen)? | Yes | |
| 9.02 | If extended BUDs are used, list products with Extended BUDs and maximum BUD in notes. | | Methylcobalamin 20% extended to 180 days, hydroxyprogesterone extended to 120 days. BUDs validated by Eagle Analytical Labs. |
| 9.03 | If extended BUDs are used, is further testing being performed to justify the use of extended BUDs? *List the types of testing performed (potency, sterility, stability, etc).* | Yes | Sterility, stability, potency. |
| 10.00 | Does the pharmacy provide sterile compounded preparations to be administered via an implantable infusion pump? | No | |
| 11.00 | Does the pharmacy perform compounding for immediate use? *Indicate percentage of immediate use sterile compounding.* | No | 0% |
| 12.00 | Does the pharmacy perform compounding with hazardous drugs? *Indicate percentage of hazardous sterile compounding.*<br>*NIOSH list of hazardous drugs including chemotherapy, hormones, etc.* | Yes | 30% |
| 12.01 | Does pharmacy have a plan to comply with USP Chapter <800> by the implementation date? *Describe plan.* | Yes | |
| 12.02 | Are hazardous drugs segregated and stored in a room that is negative pressure (at least -0.01" wc) to adjacent areas and with at least 12 ACPH? | Yes | |

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| | | Finding | Notes |
|---|---|---|---|
| 12.03 | Is hazardous drug waste quarantined in a designated area and disposed of in compliance with local, state, and federal regulations? | Yes | |
| 13.00 | Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)? *Verify that personnel can access them and are familiar with the format.* | Yes | |
| 14.00 | Does the pharmacy perform compounding using blood products (or other biological materials)? Such as wound care, autologous eye drops, etc. *Describe.* | Yes | Autologous serum eye drops for Sjogren Syndrome - separate hood used for blood products and stored in separate fridge. |
| 15.00 | Does the pharmacy compound using any Federally controlled substances I-V? *Indicate individual substances used and percentage of controlled substance sterile compounding* | Yes | Ativan, diazepam, tramadol, zolpidem. 10% is CS sterile compounding. |
| 16.00 | APIs: Does the pharmacy make any sterile compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)? | Yes | Methylcobalamin, TriMix, Hydroxyprogesterone. |
| 16.01 | Does the pharmacy purchase APIs directly from the manufacturer/repackager? *If not, indicate the source of APIs* | Yes | |
| 16.02 | Does the pharmacy verify that the manufacturer/repackager of the API is an FDA-registered facility? *If so, list how this verified* | Yes | FDA website |
| 16.03 | Does the pharmacy use active ingredients that are not from an FDA facility? *If so, indicate sources.* | No | |
| 16.04 | Does the computer track on-hand quantities of APIs used for compounding? | Yes | |
| 17.00 | Does the pharmacy use scales/balances for sterile compounding? | Yes | |
| 17.01 | If so, what type of scale/balanced is used? *List manufacturer and model number.* | | Ohaus Explorer |
| 17.02 | If the scale/balance is electronic, does the pharmacy use the automatic calibration? *Describe process and indicate frequency.* | Yes | Daily |
| 18.00 | Does the pharmacy have a lyophilizer? | No | |

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| | | Finding | Notes |
|---|---|---|---|
| 18.01 | Where is the lyophilizer located? *Indicate location and ISO class of room.* | | |
| 18.02 | Note the products lyophilized, and the volume or percent of products per week produced using the lyophilizer. | | |
| 18.03 | Is the lyophilizer part of the viable air and surface sampling, media fill testing procedures, and cleaning schedules and procedures? | N/A | |
| 19.00 | Does the pharmacy perform any testing in-house (not sent to an outside lab)? *If so, what tests are performed in-house?* | Yes | Gloved fingertip testing, surface sampling, air sampling. |
| 20.00 | Does the pharmacy send samples to an outside lab to perform testing? *If so, provide the name of the lab performing testing for the pharmacy and what testing is performed.* | Yes | Eagle Labs |
| 21.00 | Quality Assurance/Quality Improvement: Does the pharmacy continuous quality improvement program include sterile compounding measures?<br>*Note: if the facility indicates "yes", please ask each question below to verify.* | Yes | |
| 21.01 | Does the pharmacy continuous quality improvement program include QREs related to the preparation of compounded products? | Yes | |
| 21.02 | Does the pharmacy continuous quality improvement program include nonviable environmental monitoring and testing? | Yes | |
| 21.03 | Does the pharmacy continuous quality improvement program include viable environmental testing? | Yes | |
| 21.04 | Does the pharmacy continuous quality improvement program include personnel testing and verification? | Yes | |
| 21.05 | Does the pharmacy continuous quality improvement program include equipment calibration, testing, etc? | Yes | |
| 21.06 | Does the pharmacy continuous quality improvement program include sterilization method testing and validation? | Yes | |
| 21.07 | Does the pharmacy continuous quality improvement program include end product testing (such as: potency, particulates, sterility, endotoxin, etc.)? | Yes | |

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| | | Finding | Notes |
|---|---|---|---|
| 21.08 | Does the pharmacy continuous quality improvement program include patient or prescriber reports or complaints regarding CSPs? | Yes | |
| 21.09 | Does the facility QA program identify action limits or thresholds and the appropriate follow-up mechanisms when action limits or thresholds are exceeded including a recall system? | Yes | |
| 21.10 | Does the recall system include communication with both the patient and the physician/prescriber regarding the potentially contaminated CSP administered and the potential risks? | Yes | |
| 21.11 | Are QAEs involving CSPs that may have been contaminated or are recalled reported to the appropriate agency such as the Board of Pharmacy and/or FDA. | Yes | |
| 21.12 | Are all CFUs detected by any personnel, environmental, or product testing; or any other checks or tests including endotoxin, purity, potency, etc. remediated, appropriately investigated, cause determined, and processes implemented to prevent in the future, where applicable? *Review QA trends.* | Yes | |
| | **Component Selection and Use** | | |
| | **Total Non-Compliant (includes Unknowns)** | **0** | |
| 22.00 | Active Pharmaceutical Ingredients (APIs), bulk drug substances:<br>All bulk drug substances (APIs) used are:<br>1) Compliant with the standards of an applicable USP or NF monograph, if one exists; or<br>2) A component of an FDA-approved human drug product; or<br>3) On the list of bulk drug substances for use in compounding developed by the FDA and issued through regulation (note: must comply with (1) or (2) above until the FDA list is issued) | Compliant | |
| 22.01 | Certificates of analysis (COAs) obtained for all bulk APIs used for compounding. *Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.* NOTE: The COA for an API should be reviewed upon receipt of the API to verify the quality of the API before being used for compounding. | Compliant | |
| 22.02 | USP- or NF-grade substances used, if available. | Compliant | |
| 22.03 | If compendia quality components are not available, chemically pure, analytical reagent grade or American Chemical Society-certified components are used and are determined to be free from impurities. | Compliant | |

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| | | Finding | Notes |
|---|---|---|---|
| 22.04 | APIs or other components have labeling indicating use for pharmaceutical compounding or manufacturing. Labels do not indicate "for research purposes only", "not for drug use", or are handwritten labels from other pharmacies. *Photograph and describe if found. Request copies of the invoices for products with questionable labels* | Compliant | |
| 22.05 | If compounding for both humans and animals, APIs or other components that are labeled for veterinary use only are segregated or marked in such a way to prevent them from being used for human compounding. | N/A | |
| 22.06 | All substances and components have a complete label including a batch control or lot number, and an expiration date. | Compliant | |
| 22.07 | For APIs without an expiration date assigned by the manufacturer or supplier, the pharmacy assigns a conservative expiration date. The expiration date assigned is not greater than one (1) year, unless it is supported with data and/or testing. *Note: purity and quality testing may be performed to extend.* | Compliant | |
| 22.08 | All APIs are labeled with the date they were received. | Compliant | |
| 22.09 | If the pharmacy repackages APIs into smaller containers for ease of use, the expiration date assigned is conservative (typically the lesser of one year or the actual expiration from the original container). Product may be tested to extend the expiration date but may not exceed the original package expiration date. | N/A | |
| 22.10 | Bulk component containers are labeled with appropriate OSHA hazard communication labels and hazardous substances are segregated (including hormones). | Compliant | |
| 23.00 | There are no preparations for human use made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons (facility has a copy of the list or other way to determine). | Compliant | |
| 24.00 | When manufactured products are used for compounding, all the other excipients (in addition to the active ingredient) in the manufactured product are considered relative to the use, effectiveness, and stability of the compounded preparation to be made. | Compliant | |
| 25.00 | For animal compounding, does the compounding meet the same standards as compounding for human patients? | N/A | |

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# Verified Pharmacy Program® Inspection Form

## Sterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

**Facility Name:** Town Total Compounding Centers, LLC dba Town Total Compounding Center
**e-Profile ID:** 824605
**Inspection Date:** 06/02/2021 - 06/03/2021

| | | Finding | Notes |
|---|---|---|---|
| 25.01 | The pharmacist is knowledgeable or has the most up-to-date references regarding the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used. | N/A | |
| 25.02 | It is determined and documented if the animal is used for food (meat, milk, eggs, etc.) or that the animal is a pet. | N/A | |
| 25.03 | The pharmacist familiar with, or has the most up-to-date reference regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals. | N/A | |
| 25.04 | The facility has a list of drugs and components not allowed when compounding for food-producing animals. | N/A | |
| 25.05 | The pharmacist is familiar with, or has the most up-to-date reference regarding regulations for drug use in performance animals (e.g., race or show horses, racing dogs) | N/A | |
| 26.00 | If the pharmacy compounds stock solutions or components (that are then used to compound a finished product) using APIs, these stock solutions are categorized as high-risk compounding. | N/A | |
| 26.01 | The stock solutions are assigned BUD based on the USP<797> high-risk compound BUD, OR are assigned on the basis of direct testing or extrapolation from reliable literature sources to support an extended BUD. | N/A | |
| 26.02 | Compounded preparations using the stock solution are classified as high-risk compounds with appropriate handling with regard to BUD and testing requirements. | N/A | |
| **Environment** | | | |
| | **Total Non-Compliant (Includes Unknowns)** | **0** | |
| 27.00 | If the facility performs both sterile and nonsterile compounding, the areas are separated and distinct. | Compliant | |
| 28.00 | If the facility performs compounding using blood products (or other biological materials), this compounding area is separate and distinct from the general compounding areas. | Compliant | |
| 28.01 | Are components used in compounding with blood products restricted to the blood compounding area (not used in other compounding areas)? | Compliant | |
| 29.00 | Entry into the sterile compounding areas is limited to task critical employees (limited to only the pharmacist(s) and other trained and authorized pharmacy personnel). | Compliant | |

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| 30.00 | The anteroom has a line of demarcation or other separation of the dirty to the clean side. Note: the line of demarcation may NOT be the doorway between the anteroom and the clean/buffer room. | Compliant | |
| 30.01 | Carts used to bring supplies from the storeroom are kept on the outside of the line of demarcation. | Compliant | |
| 30.02 | Carts used in the clean/buffer room are kept on the clean side of the line of demarcation. | Compliant | |
| 31.00 | All surfaces of the sterile product compounding area carts, shelves, stools, chairs, and other items are resistant to disinfectants, non-permeable, non-carpeted or upholstered, and low particulate generating. | Compliant | |
| 32.00 | Walls are constructed of durable material, which is cleanable, such as epoxy-coated or heavy-gauge polymer material. *If panels are used, they are locked together and sealed.* | Compliant | |
| 33.00 | The ceiling surface shall be impervious and hydrophobic. *If tiles are used, they shall be locked and the seams between the tiles and where they meet the walls shall be caulked and sealed.* | Compliant | |
| 34.00 | The floor overlaid with wide sheet flooring and seamless or with heat welded seams, with coving to the sidewall, and a sealed seam where the coving meets the wall. | Compliant | |
| 35.00 | The clean/buffer room or anteroom does not have dust collecting overhangs. | Compliant | |
| 36.00 | The exposed surfaces of: | | |
| 36.01 | PEC are free of dirt, rust, chips and particulate matter. | Compliant | |
| 36.02 | Light fixtures are smooth, mounted flush, and sealed. | Compliant | |
| 37.00 | A working sink, located on the clean side of the line of demarcation, is available that enables pharmacy personnel to wash hands and enter the sterile compounding area without contaminating his/her hands and is away from/not adjacent to any PEC(s). | Compliant | |
| 38.00 | There is no sink or drain in the clean/buffer room. | Compliant | |
| 39.00 | Hand drying is with lint-free disposable towels, or an electronic or HEPA filtered hand dryer. | Compliant | |
| 39.01 | If using a hand dryer, particle count and smoke testing validation is performed while dryer is in use (while someone is actively using to dry their hands) at certification, and the immediate area around the dryer is part of the viable air and surface testing program performed. *(N/A if only using towels)* | N/A | |

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**Facility Name:** Town Total Compounding Centers, LLC dba Town Total Compounding Center
**e-Profile ID:** 624605
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| | | Finding | Notes |
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| 40.00 | All air ducts controlling air flow into the sterile compounding clean/buffer room and anteroom are equipped with High Efficiency Particulate Air filtered air that maintains the cleanroom with an ISO Class 7 environment and the anteroom with an ISO Class 7 (when adjacent to HD cleanroom) or ISO Class 8 environment. | Compliant | |
| 41.00 | Incoming air ducts through HEPA filters are on or near the ceiling and air return ducts are low on the walls in the anteroom and clean/buffer room. | Compliant | |
| 42.00 | If there are particle generating equipment/appliances in the clean/buffer room or anteroom (e.g. computers, printers, refrigerators, dishwashers, etc), they are located by an air return so air flows over and out of the room taking particles with it, and this air flow has been confirmed by smoke testing while in use. | Compliant | |
| 43.00 | Beverages including drinking water, chewing gum, candy, or food items are prohibited from the clean/buffer room or anteroom. | Compliant | |
| 44.00 | If compounding occurs using nonsterile ingredients, products, components, or devices (for example compounding with non-sterile APIs or using nonsterile vials and closures), the pharmacy has appropriate equipment to sterilize the finished product. | Compliant | |
| 44.01 | Pre-sterilization procedures for high risk level CSPs (such as weighing and mixing) are performed in no worse than an ISO Class 8 environment. | Compliant | |
| 45.00 | Completely enclosed anteroom and clean/buffer room (with a door) are equipped with monitors or gauges to measure differential pressure. | Compliant | |
| 45.01 | Anteroom is at least 0.02" wc positive pressure to general pharmacy areas. | Compliant | |
| 45.02 | Clean/buffer room is at least 0.02" wc positive pressure to Anteroom. | Compliant | |
| 45.03 | Hazardous compounding room and drug storage area is at least 0.01" wc negative pressure to ISO Class 7 anteroom. | Compliant | |
| 45.04 | Pressures are reviewed and documented on a log at least every work shift (minimum of once daily) or monitored by a continuous recording device.<br>*View logs* | Compliant | Both |
| 45.05 | Written plan in place to detect and react to pressure differentials outside of limits. | Compliant | |

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| | | Finding | Notes |
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| 46.00 | If the clean/buffer room and anteroom are not fully enclosed (open or with plastic strips - no door that closes), the air flow is measured across the openings. | n/a | |
| 46.01 | The air flow is at least 40 feet per minute across the entire opening. | Compliant | |
| 46.02 | Airflow is read and recorded each shift (minimum of once daily) or continuously recorded. *View logs.* | Compliant | |
| 46.03 | Written plan in place to detect and react to air flow measurements outside of limits | Compliant | |
| 46.04 | This area is used only for low- and medium-risk compounding (HD and high-risk not allowed). | Compliant | |
| 47.00 | **Temperature:** The temperature of all compounding and drug storage areas shall be maintained in accordance with standards, and a written plan shall be in place and followed to address any excursions. | Compliant | 20.1 C |
| 47.01 | Temperature in the compounding area is maintained to provide comfortable working conditions for compounding personnel of 20° C or cooler (68° F or cooler); Temperature can be more restrictive if warranted by specific drug product storage requirements. *Temperature records are maintained.* | Compliant | 20.2 C |
| 47.02 | If drugs are stored in the compounding area, temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. *Temperature records are maintained.* | Compliant | Continuous by Lighthouse and manual daily. |
| 47.03 | Temperature monitoring is also performed in drug storage areas (if separate from the compounding areas). Temperature is maintained at controlled room temperature of 20° - 25° C (68° - 77° F) or as specified by FDA approved labeling for drug product storage. | Compliant | 20.2 C |
| 47.04 | Temperature monitoring in the drug storage area is performed at least once daily and documented. *Temperature records are maintained.* | Compliant | |
| 47.05 | Temperature in the refrigerator or cooler is maintained to provide controlled cold temperature of 2° to 8°C (36° to 46°F) or as specified by FDA approved labeling for drug product storage. | Compliant | 2.6 C |

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| | | Finding | Notes |
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| 47.06 | Temperature monitoring in the refrigerator is performed at least once daily and documented. Additionally, compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberration. Alternatively, continuous monitoring or retroactive detection using min/max may be used. *Temperature records are maintained.* | Compliant | Continuous by Lighthouse and manual daily. |
| 47.07 | Temperature in the freezer is maintained to provide controlled frozen temperature of -25° to -10°C (-13° to 14°F) or as specified by FDA approved labeling for drug product storage. | Compliant | Recorded as -18.2C. |
| 47.08 | Temperature monitoring in the freezer is performed at least once daily and documented. Additionally, compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberration. *Temperature records are maintained.* | Compliant | Continuous by Lighthouse and manual daily. |
| 47.09 | Action plan in place for any temperature excursions including evaluating excursion effects on drug product integrity for all temperature monitored areas. | Compliant | |
| 48.00 | Humidity: If warranted by specific drug products, humidity in the compounding area is maintained to provide humidity within the specified ranges. If drug products require storage in a "dry place", humidity is not to exceed 40%. *[Generally recommended range is 35-60% for performing sterile compounding.]* | Compliant | 53.1 RH |
| 48.01 | If applicable, humidity monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained. | Compliant | By Lighthouse continuously. |
| 48.02 | If applicable, excursion action plan in place including evaluating excursion effects on drug product integrity. | Compliant | |
| 48.03 | If applicable, humidity monitoring is also performed in drug storage areas (if separate from the compounding areas). | Compliant | |
| 49.00 | Blowers on ISO 5 PECs are operated continuously during compounding activity, including during interruptions of less than eight hours. | Compliant | |
| 50.00 | When the ISO 5 PEC blower is turned off, and before other personnel enter to perform compounding activities, only one garbed person is allowed to enter the buffer area for the purposes of turning on the blower (for at least 30 minutes) and of sanitizing the work surfaces. | Compliant | |

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| | | Finding | Notes |
|---|---|---|---|
| 51.00 | The doors into the anteroom from the general pharmacy area and from the anteroom into the clean/buffer room are prevented from both being open at the same time. *By interlocking, training of personnel, or signage.* | Compliant | |
| 52.00 | The inside and outside doors of a pass-through are prevented from both being open at the same time. *By interlocking, training of personnel, or signage.* | Compliant | |
| 53.00 | If the PEC is a BSC or LAFW that is NOT located in an ISO Class 7 clean/buffer room: BSC or LAFW has been certified to maintain ISO Class 5 during compounding activities. | N/A | |
| 53.01 | Used only for low-risk compounded preparations with a 12-hour or less BUD assigned. *If yes, list percentage.* | N/A | |
| 53.02 | All garbing requirements are adhered to. | N/A | |
| 53.03 | Located in an area that is maintained under sanitary conditions and only traveled by persons engaging in the compounding of sterile preparations. | N/A | |
| 53.04 | Location does not contain any unsealed windows or doors that connect to the outdoors or areas of high traffic flow, and is not adjacent to construction sites, warehouses, or food preparation areas? | N/A | |
| 53.05 | The sink is separated from the immediate area of the ISO Class 5 BSC or LAFW (not adjacent). | N/A | |
| 54.00 | If the PEC is a CAI/CACI that is NOT located in an ISO Class 7 clean/buffer room: CAI/CACI has been certified to maintain ISO Class 5 under dynamic conditions including transferring of ingredients, components and devices, and during preparation of CSP. | N/A | |
| 54.01 | The pharmacy has documentation from the manufacturer that the CAI or CACI will meet this standard when located in worse than ISO Class 7 environments. | N/A | |
| 54.02 | The CAI or CACI is located in an area that is maintained under sanitary conditions and only traveled by persons engaging in the compounding of sterile preparations. | N/A | |
| 54.03 | The sink is separated from the immediate area of the CAI or CACI (not adjacent). | N/A | |
| 54.04 | For NIOSH hazardous compounding in a CACI that is NOT located in a clean/buffer room, the CACI is located in a physically separated area that maintains a negative pressure of 0.01" water column pressure to adjacent areas and a minimum of 12 ACPH. | N/A | |

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| | | Finding | Notes |
|---|---|---|---|
| **Cleaning and Disinfection** | | | |
| | **Total Non-Compliant (Includes Unknowns)** | **0** | |
| 55.00 | Are all personnel performing cleaning appropriately garbed? | Compliant | |
| 56.00 | Is the sterile compounding area equipped with appropriate nonshedding cleaning equipment and supplies?<br>*All cleaning tools, such as wipers, sponges, and mops, must be nonshedding, dedicated to and labeled for use in either the buffer or clean area (no wooden handles are allowed).* | Compliant | |
| 57.00 | If cleaning tools are reused, is there a procedure to rinse and sanitize the tools and an appropriate clean storage area? | Compliant | |
| 58.00 | Are reusable tools appropriately labeled to prevent them from being used inappropriately? | Compliant | |
| 59.00 | For cleaning and sanitizing agents that are not "ready-to-use" formulations, are there formulas and instructions for mixing or diluting the agents prior to use and is the preparation documented? | N/A | all formulations are RTU |
| 60.00 | Are cleaning and sanitizing agents appropriately labeled including expiration dates?<br>*Verify no expired agents present.* | Compliant | |
| 61.00 | Are appropriate cleaning agents used that are effective for bacteria, viruses, fungi, and spores? | Compliant | |
| 62.00 | Is the ISO 5 PEC cleaned at the beginning of each shift, between compounding activities, at least every 30 minutes while compounding and after spills or suspected surface contamination? | Compliant | |
| 62.01 | If heavily soiled, cleaning includes the appropriate agent. *List agent[s] used.* | Compliant | Sterile alcohol. |
| 63.00 | Does sanitizing of the ISO 5 PEC include sanitizing with sterile 70% IPA using a nonlinting wipe? | Compliant | |
| 64.00 | Does daily cleaning and sanitizing include counters and easily cleanable work surfaces? | Compliant | |
| 65.00 | Does daily cleaning include the floors starting from the clean/buffer room and working outwards? Floor cleaning is not to occur during compounding. | Compliant | |

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| 66.00 | If fatigue mats are used, are they cleaned daily and let dry on both sides? | N/A | |
| 67.00 | Is a tacky mat used and if so, is there a procedure in place regarding replacement? | Compliant | Permanent Dycem floor system. |
| 68.00 | Are the ceilings, walls, all shelving, bins, carts, chairs, and the tops and sides of the primary engineering controls (PECs) thoroughly cleaned monthly? *(This includes removing everything from shelves and bins before cleaning, cleaning the undersides of cart surfaces and stools, wheels, etc.) Check inside bins and shelving for dust if you are garbed.* | Compliant | |
| 69.00 | Is enough time allocated for cleaning activities, including contact/dwell times for the cleaning/disinfection agents? | Compliant | |
| **Training** - *Verify records of all compounding personnel (up to 10).* | | | |
| | **Total Non-Compliant (Includes Unknowns)** | 0 | |
| 70.00 | There is documentation that compounding personnel are appropriately trained including policies and procedures, documentation, hazardous drug handling, cleaning/disinfection/spills, garbing/gowning/hand hygiene, and aseptic technique. *Note that "compounding personnel" includes personnel performing compounding, supervising compounding, and performing verification of compounding. List number of personnel training files viewed.* | Compliant | 7 files |
| 70.01 | All personnel performing compounding are not allowed to compound until training and initial testing is successfully completed. | Compliant | |
| 70.02 | All personnel that SUPERVISE compounding and/or perform verifications of other's compounding are not allowed to supervise or verify compounding until training and initial testing is successfully completed. | Compliant | |
| 71.00 | All personnel of reproductive capability who handle or compound hazardous drugs or chemicals have confirmed in writing that they understand the risks of handling hazardous drugs. *Teratogenicity, carcinogenicity, reproductive issues.* | Compliant | |
| 72.00 | There is documentation, such as an observational checklist, that all personnel (including housekeeping or other outside personnel) that perform cleaning activities in the compounding areas including hazardous compounding areas are appropriately trained in garbing, cleaning and disinfection. | Compliant | |

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| 73.00 | There is documentation of training on the operation of any equipment that may be used when preparing compounded sterile products.<br>*Documentation needs to include training on operation, and troubleshooting* | Compliant | |
| 74.00 | If the pharmacy uses relief personnel from outside agencies to perform sterile compounding, training and certifications are verified.<br>*View documentation.* | n/a | |
| 75.00 | There is documentation that all compounding personnel (including those supervising or performing verifications) have passed an initial written exam, and subsequent annual written exams for the appropriate compounding risk levels and NIOSH hazardous drugs when applicable. *Indicate frequency, if testing more than annually.* | Compliant | |
| 76.00 | There is documentation that all compounding personnel have passed an initial and subsequent annual competency assessments of aseptic compounding skills using observational audit tools including handling NIOSH hazardous drugs when applicable. Compounding skills evaluation to include use of equipment. *Indicate frequency, if testing more than annually.* | Compliant | |
| 77.00 | There is documentation that new compounding personnel have passed an initial observed gowning procedure and three gloved fingertip sampling tests? *Personnel must pass the tests upon initial validation before being allowed to compound. Action required if the tests yield any garbing deficiencies, or if the sampling results are >0 colony-forming units (CFU)/plate on the three initial validations. Indicate frequency, if testing more than annually.* | Compliant | Every 6 months |
| 78.00 | There is documentation that compounding personnel preparing low or medium risk-level products have passed an annual observed gowning procedure and gloved fingertip sampling test. *Action required if the tests yield any garbing deficiencies, or if the fingertip sampling results are >3 CFU (total both hands, all 10 fingers). Documentation to include type of media used, COA on media, incubation time and temperature and interpretation of results. Indicate frequency, if testing more than annually.* | Compliant | Every 6 months |

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| 79.00 | There is documentation that a media fill test procedure is performed for each compounding employee at least annually for individuals that prepare low or medium risk-level products. *The test conditions must closely simulate the most challenging or stressful conditions encountered during compounding of the highest risk level product and include any automation used in compounding. Media-filled vials are incubated and failure is indicated by visible turbidity in the medium on or before 14 days. Indicate frequency, if testing more than annually.* | Compliant | Every 6 months |
| 80.00 | The media-fill testing procedures include: | | |
| 80.01 | Media selection (including obtaining COAs or growth promotion certificates from suppliers) | Compliant | |
| 80.02 | Fill Volume | Compliant | |
| 80.03 | Incubation time and temperature (Media-filled vials are generally incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature.) | Compliant | |
| 80.04 | Inspection of filled units | Compliant | |
| 80.05 | Documentation | Compliant | |
| 80.06 | Interpretation of results | Compliant | |
| 80.07 | Action levels set with the corrective actions required | Compliant | |
| 81.00 | **High-Risk Sterile Compounding:** There is documentation that compounding personnel have passed an observed gowning procedure and gloved fingertip sampling test every six (6) months. *Action required if the tests yield any garbing deficiencies, or if the sampling results are >3 CFU on both hands upon revalidation. Documentation to include type of media used, COA on media, incubation time and temperature and interpretation of results. Indicate frequency, if testing more than every 6 months.* | Compliant | Every 6 months |
| 82.00 | **High-Risk Sterile Compounding:** There is documentation that a media fill test procedure is performed for each compounding employee at least every six (6) months for individuals that prepare high risk-level products. *The test conditions must closely simulate the most challenging or stressful conditions encountered during compounding of the highest risk level product and include any automation used in compounding. Media-filled vials are generally incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature.* | Compliant | |

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|---|---|---|---|
| 83.00 | Failed testing: Employees who have failed any testing are prohibited from compounding until training is performed/reviewed and subsequent testing is performed successfully. | Compliant | |
| 83.01 | Gloved fingertip tests that have failed have the organisms identified down to the genus to determine the most likely source of the contamination. This data is used to develop plans to prevent contamination. | Compliant | |
| 83.02 | There is a plan to evaluate the sterile compounds prepared by an employee with failed gloved fingertip tests or media fills to detect potential contamination of the sterile preparations compounded. | Compliant | |
| | **Garbing** | | |
| | **Total Non-Compliant (includes Unknowns)** | **0** | |
| 84.00 | Personnel are prohibited from compounding, or entering the clean/buffer room or anteroom if they have a rash, sunburn, weeping sores, conjunctivitis, or an active respiratory infection. | Compliant | |
| 85.00 | Personnel are required to remove all personal outer garments such as hats, scarves, sweaters, vests, coats, or jackets and any makeup or cosmetics before entering compounding areas. *Include observations in the comments.* | Compliant | |
| 86.00 | Personnel are required to remove all hand and wrist jewelry, and all visible jewelry or piercings such as earrings, lip or eyebrow piercings, etc. before entering clean/buffer room. | Compliant | |
| 87.00 | Personnel are prohibited from wearing artificial nails or extenders, and required to keep natural nails neat and trimmed. | Compliant | |
| 88.00 | Garbing with dedicated shoes or shoe covers that are donned as the line of demarcation is crossed (with the dedicated or covered shoe never touching the same side of the line of demarcation as the dirty shoe). | Compliant | |
| 89.00 | Garbing includes head and facial hair covers and masks.<br>*Note that facial hair requires both a facial hair cover AND a mask. Eye shields are optional unless using cleaning agents or preparing hazardous drugs. There is a method available to assure that all hair is covered.* | Compliant | |

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# National Association of Boards of Pharmacy®
# Verified Pharmacy Program® Inspection Form

## Sterile Compounding Inspection

**The information and comments obtained in the Nonsterile Compounding and Sterile Compounding inspections are based on USP Chapters <795> and <797>. An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.**

**Facility Name:** Town Total Compounding Centers, LLC dba Town Total Compounding Center
**e-Profile ID:** 824605
**Inspection Date:** 06/02/2021 - 06/03/2021

| | | Finding | Notes |
|---|---|---|---|
| 90.00 | Hand cleaning is performed in the anteroom and includes removing debris from under the nails with a nail cleaner followed by a vigorous washing of the hands and forearms with soap for at least 30 seconds with hands and arms then dried with a non-linting disposable towel or a hand dryer. *Scrub brushes are NOT recommended as they cause skin irritation and damage.* | Compliant | |
| 91.00 | The gown is nonshedding with sleeves that fit snugly around the wrists and enclosed at the neck. | Compliant | |
| 92.00 | All bare skin is covered on the arms and the legs (no bare ankles, wrists, etc.). | Compliant | |
| 93.00 | Prior to donning sterile gloves, a waterless alcohol based surgical hand scrub with persistent activity is used and hands allowed to dry. *Note: regular Purell Hand Sanitizer is NOT appropriate. Purell or other brand surgical hand scrub is appropriate - must have residual activity.* | Compliant | Purell Surgical scrub with persistent activity. |
| 94.00 | Upon leaving the sterile product compounding area, gowns are taken off and disposed of, or if used for nonhazardous compounding they are left in the anteroom and not reused for longer than one shift. | Compliant | |
| 95.00 | Pharmacists or other personnel do NOT enter the anteroom and cross the line of demarcation without donning shoe covers or dedicated shoes. *Watch for personnel traversing back and forth across the line of demarcation without doffing and donning new shoe covers or dedicated shoes.* | Compliant | |
| 96.00 | Pharmacists or other personnel do NOT enter the clean/buffer room without fully washing and garbing (wearing just a mask to check technician's work, for example) | Compliant | |
| **Environmental Monitoring** | | | |
| | **Total Non-Compliant (Includes Unknowns)** | **0** | |
| 97.00 | The most recent PEC and room certification report is available. | Compliant | |
| 97.01 | All ISO Class 7 and 8 SECs (clean/buffer rooms and anterooms) have been certified within the last 6 months. *If non-compliant, record the date of the last certification.* | Compliant | |
| 97.02 | All ISO Class 5 PECs (laminar airflow workbenches or areas, BSCs, CAIs, CACIs, and barrier isolators) have been certified within the last 6 months. *If non-compliant, record the date of the last certification.* | Compliant | |

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| | | Finding | Notes |
|---|---|---|---|
| 97.03 | Certification is performed at least every six months (view date of previous certification) and whenever a device or room is relocated or altered, or major service to the facility is performed. *If non-compliant, record the date of the previous certification.* | Compliant | 12/18/2020 by Charles Solana and Sons. |
| 97.04 | Certification is performed to the Controlled Environment Testing Association (CETA) guide (USP: CETA CAG-003-2006 Certification Guide for Sterile Compounding Facilities) and is noted on the report. | Compliant | |
| 97.05 | If the certification standard used and noted on the report is NOT CETA CAG-003-2006, the facility has performed a comparison and determined the standard used is the same or better than the CETA CAG-003-2006 guide. | N/A | |
| 97.06 | The PIC/compounding supervisor is familiar with what testing is required and interpretation of results; ensures all testing is performed appropriately (under dynamic conditions where appropriate); has action levels identified, evaluates results to detect issues or trends, and action levels are further customized based on trended data of performance. | Compliant | |
| 98.00 | The certification report includes information about the equipment used for performing each test including: identification of the equipment used by model, serial number, last calibration date (or date when next calibration is due). | Compliant | |
| 98.01 | The equipment used had not exceeded its calibration date at the time of certification. | Compliant | |
| 99.00 | The HEPA filtered air changes per hour (ACPH) were measured for the compounding rooms. | Compliant | |
| 99.01 | ISO Class 7 sterile compounding room is certified as having a minimum of 30 ACPH with at least 15 ACPH from outside air sources. *Recirculated air from the PECs may account for up to 15 ACPH in nonhazardous classified rooms only.* | Compliant | |
| 99.02 | ISO class 7 anteroom is certified as having a minimum of 30 ACPH. *Anteroom must be ISO class 7 if connected to a NIOSH hazardous compounding clean/buffer room.* | Compliant | |
| 99.03 | ISO class 7 hazardous sterile compounding room is certified as having a minimum of 30 ACPH. *Typically all of the air will be from outside.* | Compliant | |
| 99.04 | If a CACI is used in a non-HEPA filtered room, the room is certified to maintain a minimum of 12 ACPH. | N/A | |

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| | | Finding | Notes |
|---|---|---|---|
| 100.00 | Air pattern analysis using smoke testing was performed under dynamic conditions (people working in the PECs and rooms). The smoke flow is described in the report for the various tests such as turbulent, sluggish, smooth, etc. | Compliant | |
| 100.01 | Air pattern analysis was conducted at the critical area (direct compounding area inside the ISO Class 5 PEC) to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions (personnel compounding or simulating compounding in PEC). | Compliant | |
| 100.02 | Air pattern analysis was conducted to confirm positive pressure (and negative pressure into hazardous compounding rooms) at all points around all openings, doorways, and pass-throughs | Compliant | |
| 100.03 | Air pattern analysis conducted around particle generating equipment *while the equipment was in operation* to confirm air flow. | Compliant | |
| 101.00 | Differential air pressure between rooms was measured. | Compliant | |
| 101.01 | The differential pressure measured was at least 0.02" water column positive from the cleanroom to the anteroom and between the anteroom and all adjacent spaces with the doors closed. | Compliant | |
| 101.02 | The differential pressure measured was at least 0.01" water column negative from the hazardous clean/buffer room to the anteroom with the doors closed. | Compliant | |
| 102.00 | Displacement airflow between rooms or areas was measured. This is for a clean/buffer room without a door that closes to the anteroom - may be an open space or may have plastic strips in doorways. | N/A | |
| 102.01 | Displacement airflow (for low and medium-risk non-hazardous rooms only) was measured at a minimum differential velocity of 40 feet per minute from the cleanroom to the anteroom. *Note that it is very important to maintain this velocity across the entire opening and the report should indicate multiple points of measure across all openings.* | N/A | |
| 103.00 | Particle counts of particles 0.5um and larger were measured under dynamic conditions. | Compliant | |
| 103.01 | ISO Class 5 areas and PECs are certified as having less than 3,520 particles per cubic meter of air (100 particles per cubic foot). | Compliant | |
| 103.02 | ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air (10,000 particles per cubic foot). | Compliant | |

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| | | Finding | Notes |
|---|---|---|---|
| 103.03 | ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air (100,000 particles per cubic foot). | Compliant | |
| 104.00 | HEPA filter tests were performed. | Compliant | |
| 104.01 | All room HEPA filters were leak tested and if leaks found, they were fixed | Compliant | |
| 104.02 | All PEC HEPA filters were leak tested and if leaks found, they were fixed | Compliant | |
| 105.00 | PECs with failed tests are not used for compounding until the conditions are corrected and verified by subsequent testing. | compliant | |
| 106.00 | Viable air (every six months) and surface sampling (periodically) tests have been conducted as required. *Document frequency.* | Compliant | Viable air every 6months, surface sampling every month. |
| 106.01 | Appropriate growth media used (containing tryptic soy agar medium with polysorbate and lecithin (TSApl) added to neutralize cleaning agents for surface sampling) with appropriate corresponding incubation time and temperature used. *Required to use media that supports both bacterial and fungal growth for high risk compounding.* | Compliant | |
| 106.02 | Viable air sampling by active impaction using a volumetric air sampling device. *NOTE: Passive air sampling or settling plates are not compliant with USP Chapter <797>.* | Compliant | |
| 106.03 | Air samples were taken in each ISO Class 5 PEC, and in each sterile compounding room and anteroom and volume sufficient volume of air (400-1000L) was collected? *Note: 1000L must be collected in ISO Class 5 PECs to be able to detect the action level. Room samples can be 400-1000L.* | Compliant | |
| 106.04 | Surface samples performed on all direct compounding areas inside of each ISO 5 PEC, in each ISO classified room, inside any pass-throughs, and on surfaces likely to be contaminated due to position relative to doorways, etc. | Compliant | |

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## Sterile Compounding Inspection

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| | | Finding | Notes |
|---|---|---|---|
| 106.05 | Viable air and surface samples did not exceed USP action levels (or internal action levels if more restrictive).<br>Classification Air Sample Surface Sample<br>ISO Class 5 >1 CFU/m3 >3 CFU/plate<br>ISO Class 7 >10 CFU/m3 >5 CFU/plate<br>ISO Class 8 >100 CFU/m3 >100 CFU/plate<br>*CFUs are TOTAL of bacterial plus fungal/mold plates. If air sampling volume is less than 1000 liters (one cubic meter), the raw total microbial count must be multiplied by the appropriate factor to determine the number of CFU/cubic meter.* | Compliant | |
| 106.06 | CFUs detected by any means (viable air or surface sampling, gloved fingertip testing, failed sterility tests, etc.) are identified to the genus level. *All CFUs detected must be identified even if the number of CFUs does not exceed an action level.* | Compliant | |
| 106.07 | If the number of CFUs detected in the rooms exceeds action levels, begin immediate remediation (e.g. recleaning and retesting); and conduct investigation into the source(s) of the contamination. | Compliant | |
| 106.08 | If the number of CFUs detected in the PECs exceeds action levels, begin immediate remediation, (e.g. recleaning and retesting); and conduct investigation into the source(s) of the contamination. | Compliant | |
| 106.09 | If any highly pathogenic microbes (e.g. mold, yeast, coagulase positive staphylococcus, or gram negative rods) were detected (whether or not the number of CFUs exceeds action levels), begin immediate remediation(e.g. recleaning and retesting); and conduct investigation into the source(s) of the contamination. | Compliant | |
| 107.00 | Facilities performing routine air or surface sampling with internal qualified personnel routinely verify sampling procedures. *Indicate the suitable vendor used to verify procedures and frequency of verifications.* | Compliant | |

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## Sterile Compounding Inspection

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**Facility Name:** Town Total Compounding Centers, LLC dba Town Total Compounding Center
**e-Profile ID:** 824605
**Inspection Date:** 06/02/2021 - 06/03/2021

| | | Finding | Notes |
|---|---|---|---|
| **Equipment** | | | |
| | **Total Non-Compliant (includes Unknowns)** | 0 | |
| 108.00 | Appropriate equipment and utensils are available, clean, and in good working order. *Automated, mechanical, or electronic equipment (autoclaves, ovens, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines.* | Compliant | |
| 109.00 | All environmental monitoring equipment and gauges (differential pressure gauges or probes, air flow and velocity measuring equipment for rooms not fully enclosed, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines. Calibration is documented. | Compliant | |
| 110.00 | All temperature and humidity (where applicable) monitoring devices (thermometers, hygrometers, probes, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines. Calibration is documented | Compliant | |
| 111.00 | Automated Compounding Devices (ACDs) are used for sterile compounding (such as repeater pumps) and there is a P&P for the use and calibration. | N/A | |
| 111.01 | There is documentation of the ACD tubing being changed or discarded every 24 hours | N/A | |
| 111.02 | The ACD is used when performing media fill testing. | N/A | |
| **Compounding Procedures** | | | |
| | **Total Non-Compliant (includes Unknowns)** | 0 | |
| 112.00 | Gloves are disinfected with adequate frequency with an approved disinfectant, such as sterile 70% isopropyl alcohol (IPA). | Compliant | |
| 113.00 | Nonessential objects that shed particles are prohibited in the buffer or clean area, including pencils, cardboard cartons, paper towels, reading material, and cotton items (e.g., gauze pads)? | Compliant | Batch and compounding records are computerized with use of individual portable computers or displayed outside of clean area and viewed thru glass walls. |
| 114.00 | Essential paper related products (syringe overwraps, work records contained in a protective plastic sleeve) are wiped down with sterile 70% IPA before being brought into the buffer or clean area. | Compliant | |
| 115.00 | Supplies required for the scheduled operations of the shift are prepared by wiping the outer surface with sterile 70% IPA (or removing the outer wrap as the item is introduced into the aseptic work area) and brought into the buffer or clean area in a bin or on a movable cart. | Compliant | |

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| | | Finding | Notes |
|---|---|---|---|
| 116.00 | Compounding employees are using appropriate aseptic technique.<br>*May require inspector to garb and enter clean/buffer room. Pay attention to first air, entry and exit of materials in ISO Class 5 PEC, appropriate frequent sanitization of gloves, appropriate cleaning and cleanliness of the direct compounding area (DCA). Compounding MUST be observed. If compounding is not being performed at the time of survey mark item as "Non-Compliant".* | Compliant | |
| 116.01 | If compounding is not being performed at the time of survey, ask that a compounding pharmacist or technician prepare a compound for you to observe the compounding process. *If the pharmacy staff refuses or is unable to perform compounding for you to observe, document on the "Denial of Authorization" form. Do not allow the Denial of Authorization* | | |
| 117.00 | Compounding personnel ascertain that ingredients for CSPs are of the correct identity and appropriate quality by reading vendors' labels, and a unit-by-unit physical inspection of the product before use. | Compliant | |
| 118.00 | All rubber stoppers, of vials and bottles and the necks of ampules are disinfected with sterile 70% IPA waiting for at least 10 seconds before they are used to prepare CSPs. | Compliant | |
| 119.00 | Single-dose vials exposed to ISO Class 5 or cleaner air are used within six (6) hours of the initial puncture and any remaining contents discarded. *If exposed to less than ISO Class 5 air, used within 1 hour and discarded.* | Compliant | |
| 120.00 | The remaining contents of opened single-dose ampules (or vials where container closure system has been removed) are discarded immediately. *May not be stored for any time period.* | Compliant | |
| 121.00 | Multiple-dose vials formulated for removal of portions on multiple occasions are used within 28 days (or the manufacturer's specific BUD if less) after the initial entry or puncture and any remaining contents discarded. | Compliant | |
| 122.00 | The compounding record is complete.<br>*View several completed compounding records and answer each of the following questions. List records reviewed.* | Compliant | Atropine eye drops, cyclopentolate eye drops, amphotericin eye drops. |
| 122.01 | Official or assigned name, strength and dosage of the preparation | Compliant | |
| 122.02 | Names, lot numbers and expiration dates of all components | Compliant | |
| 122.03 | Total quantity or number of units compounded | Compliant | |

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| 122.04 | Person compounding the preparation | Compliant | |
| 122.05 | Person performing the quality control procedures | Compliant | |
| 122.06 | Person who approved the preparation | Compliant | |
| 122.07 | Date of compounding | Compliant | |
| 122.08 | Assigned internal identification number or prescription number | Compliant | |
| 122.09 | Assigned BUD and reference if extended beyond USP guidelines | Compliant | |
| 122.10 | Duplicate label | Compliant | |
| 122.11 | Sterilization method (if applicable) | Compliant | |
| 122.12 | Indication of the quality control procedures to perform (testing, filter integrity, etc.) and results of the testing, quality control issues, and investigation/recall if applicable | Compliant | |
| 123.00 | Procedure for in-process checks is followed.<br>*These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists and visual inspection of product. Documentation of the compounding accuracy is recommended to be performed by someone other than the compounder to ensure proper measurement, reconstitution, and component usage.* | Compliant | |
| 124.00 | Labels on BATCH preparations include the name and quantity of all contents, date, and time of preparation (or internal code indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials. | Compliant | |
| 125.00 | Labels on PATIENT-SPECIFIC containers, in addition to standard label requirements, also include names and quantity or concentration of active ingredients, BUD, total volume, route of administration, storage conditions and other information for safe use. | Compliant | |

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| | | Finding | Notes |
|---|---|---|---|
| 126.00 | Inspect several different finished products and look for any particulates. Do any of the finished products inspected show any evidence of particulates? *If so, list the products including lot and expiration date and obtain photos (if possible).* **REQUEST THE PRODUCT BE QUARANTINED AND NOTIFY NABP IMMEDIATELY.** | Compliant | |
| 127.00 | Preparations without additional stability testing or supported by data are assigned BUDs within USP<797> guidelines.<br>**Low Risk:** 48 hours room temp, 14 days refrigerated, 45 days frozen<br>**Medium Risk:** 30 hours room temp, 9 days refrigerated, 45 days frozen<br>**High Risk:** 24 hours room temp, 3 days refrigerated, 45 days frozen | Compliant | |
| 128.00 | If extended BUDs are assigned, are they assigned on the basis of stability data extrapolated from reliable literature sources? *View records, preparation must exactly match the preparation tested in the documentation including concentration of all active ingredients, excipients, etc.* | Compliant | From manufacturer or PCCA studies. |
| 129.00 | If extended BUDs are assigned, has the facility performed its own stability testing? *View records, preparation must exactly match the preparation tested by the facility including concentration of all active ingredients, excipients, etc. If so, view records for at least three products and list the products reviewed below. List the products reviewed.* | Compliant | Eagle Labs - BUD studies- Atropine 0.02% eye drops= BUD =60 days; Methylcobalamin Inj - BUD 180 days. |
| 130.00 | Compounded multiple-dose vials with extended BUDs assigned have additional instruction provided that indicates remainder must be discarded 28 days after first puncture or use. | N/A | |
| 131.00 | Filter sterilization in an ISO 5 environment and documentation includes: | | |
| 131.01 | If the compounded preparation contains large particles, a prefilter is placed upstream from the sterilizing filter. | Compliant | |
| 131.02 | The 0.2 micron sterile microporous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSPs and the filter is intended for human use applications for sterilizing CSPs (labeling on the filter does not indicate "research only" or "laboratory only", for example). | Compliant | |
| 131.03 | Is the appropriate capacity filter being used for the volume being filtered. | Compliant | |
| 131.04 | Filtering is completed rapidly without filter replacement. | Compliant | |

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| | | Finding | Notes |
|---|---|---|---|
| 131.05 | Confirmation of filter integrity/bubble testing is performed and value documented for each filter used with each batch sterilized by filtration. View documentation on compounding records of items sterilized by filtration to confirm. | Compliant | |
| 132.00 | **Steam sterilization documentation includes:** | | |
| 132.01 | The autoclave has been verified for the exposure time and mass of the items to be sterilized | Compliant | |
| 132.02 | Ensures live steam contacts all ingredients and surfaces to be sterilized, effectiveness verified with biological indicators and temperature sensing devices | Compliant | |
| 132.03 | Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization | Compliant | |
| 132.04 | That the CSP will not be adversely affected by the steam and heat | Compliant | |
| 132.05 | The description of steam sterilization includes conditions and duration for specific CSPs | Compliant | |
| 132.06 | That the effectiveness of steam sterilization is verified each time using appropriate biological indicators of Bacillus stearothermophilus and other confirmation methods such as temperature-sensing devices. | Compliant | |
| 133.00 | **Dry heat sterilization documentation includes:** | | |
| 133.01 | Dry heat is only used for those items that cannot be sterilized by steam or would be damaged by moisture | Compliant | |
| 133.02 | Sufficient space is left between materials to allow for air circulation | Compliant | |
| 133.03 | The description of dry heat sterilization includes conditions and duration for specific CSPs | Compliant | |
| 133.04 | That the effectiveness of dry heat sterilization is verified each time using appropriate biological indicators of Bacillus subtilis and other confirmation methods such as temperature-sensing devices. | Compliant | |
| 133.05 | Heated filtered air is evenly distributed throughout the chamber with a blower and the oven is equipped with a system for controlling and recording temperature and exposure period. | Compliant | |
| 134.00 | **Depyrogenation by dry heat documentation includes:** | | |

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# National Association of Boards of Pharmacy®
# Verified Pharmacy Program® Inspection Form

## Sterile Compounding Inspection

**The information and comments obtained in the Nonsterile Compounding and Sterile Compounding inspections are based on USP Chapters <795> and <797>. An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.**

**Facility Name:** Town Total Compounding Centers, LLC dba Town Total Compounding Center
**e-Profile ID:** 824605
**Inspection Date:** 06/02/2021 - 06/03/2021

| | | Finding | Notes |
|---|---|---|---|
| 134.01 | Dry heat depyrogenation is used to render glassware and containers (such as vials) free from pyrogens as well as viable microbes. | Compliant | |
| 134.02 | The description of the cycle and duration for specific load items | Compliant | |
| 134.03 | The effectiveness of the cycle is verified using endotoxin challenge vials (ECVs) | Compliant | |
| 134.04 | Bacterial endotoxin testing is performed on the ECVs to verify the cycle is capable of achieving a 3-log reduction in endotoxins | Compliant | |
| 135.00 | Other methods of sterilization are used with documented procedures and validation performed. *Indicate method.* | n/a | |
| **Finished Preparation Release Checks and Tests** | | | |
| | **Total Non-Compliant (includes Unknowns)** | **0** | |
| 136.00 | Are products visually checked for particulates or other foreign matter against both a light and a dark colored background as a condition of release? | Compliant | |
| 137.00 | Are there checks for container, closure integrity and any other apparent visual defects? | Compliant | |
| 138.00 | Is compounding accuracy documented by verification of steps? | Compliant | |
| 139.00 | Is verification of ingredient identity and quantity verified? *Is there a reconciliation of components?* | Compliant | |
| 140.00 | Are labels verified as being correct and is a copy of the label included in the record? *Complies to regulation, contains the correct names and amounts or concentrations of ingredients, total volumes, BUDs, storage conditions, and route of administration.* | Compliant | |
| 141.00 | Sterility testing (USP <71>). *If testing is performed to a lesser standard than the initiatives below, describe.* | | |
| 141.01 | Sterility testing includes both bacterial and fungal testing. | Compliant | |
| 141.02 | Sterility testing is performed for all CSPs that have extended BUDS. | Compliant | |
| 141.03 | Sterility testing is performed for high-risk CSPs prepared in batches of more than 25 identical containers | Compliant | |

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# National Association of Boards of Pharmacy®
# Verified Pharmacy Program® Inspection Form

## Sterile Compounding Inspection

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**Facility Name:** Town Total Compounding Centers, LLC dba Town Total Compounding Center
**e-Profile ID:** 824605
**Inspection Date:** 06/02/2021 - 06/03/2021

| | | Finding | Notes |
|---|---|---|---|
| 141.04 | Sterility testing is performed for CSPs exposed longer than 12 hours at 2°C-8°C or longer than six hours at warmer than 8°C before being sterilized | Compliant | |
| 141.05 | The appropriate quantities of units are sterility tested.<br>Parenterals, number of units in the batch is:<br>1. Not more than 100, test 10% or four units, whichever is greater<br>2. More than 100 but more than 500, test 10 units<br>3. More than 500, test 2% or 20 units, whichever is less<br>For large volume parenterals: 2% or 10 containers, whichever is less.<br>For non-parenterals (eye drops, inhalation, etc.):<br>1. Not more than 200 containers, test 5% or 2 containers, whichever is greater<br>2. More than 200, test 10 containers<br>3. If the product is packaged in unit doses, use the parenteral testing above. | Compliant | |
| 141.06 | For products failing testing, product is quarantined, and an investigation is performed including microbial identification and action taken. *View testing records and note any products with failed results and actions taken.* | N/A | No failed tests. |
| 141.07 | If items are dispensed or distributed prior to sterility testing completion, there is a written procedure requiring daily observation of the incubated media. If there is any evidence of microbial growth, there is an immediate recall and both the patient and the physician/prescriber of the patient to whom a potentially contaminated CSP was administered are notified of the potential risk. *View testing records and note any products with failed results and actions taken.* | N/A | |
| 142.00 | **Endotoxin testing (USP <85>).** *If testing is performed to a higher standard than the requirements below, describe.* | | |
| 142.01 | Is endotoxin testing performed for all high-risk level CSPs for administration by injection prepared in groups of more than 25 single-dose packages (such as ampules, bags, syringes, vials) | Compliant | |
| 142.02 | High-risk CSPs prepared in multiple dose vials for administration to multiple patients | Compliant | |
| 142.03 | High-risk CSPs exposed longer than 12 hours at 2°C-8°C (25°F-46°F) or longer than six (6) hours at warmer than 8°C (46°F) before they are sterilized | Compliant | |
| 142.04 | For products failing testing, product is quarantined, and an investigation is performed and action taken. *View testing records and note any products with failed results and actions taken.* | Compliant | No failed tests. |

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# National Association of Boards of Pharmacy®
# Verified Pharmacy Program® Inspection Form

## Sterile Compounding Inspection

**The information and comments obtained in the Nonsterile Compounding and Sterile Compounding inspections are based on USP Chapters <795> and <797>.**
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**Facility Name:** Town Total Compounding Centers, LLC dba Town Total Compounding Center
**e-Profile ID:** 824605
**Inspection Date:** 06/02/2021 - 06/03/2021

| | | Finding | Notes |
|---|---|---|---|
| **Patient Counseling and Communication** | | | |
| | **Total Non-Compliant (Includes Unknowns):** | **0** | |
| 143.00 | Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of hazardous products such as chemotherapy medications? | Compliant | |
| 144.00 | Are the above required printed drug information materials (drug information, PPI, MedGuides, etc.) provided for the compounded products? | Compliant | |
| 145.00 | Are patients instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy? | Compliant | |
| 146.00 | Product recalls include documentation that both the patient AND the physician/prescriber of the potentially contaminated CSP was administered are notified of the potential risk. | Compliant | |

**The information and comments obtained in the Nonsterile Compounding and Sterile Compounding inspections are based on USP Chapters <795> and <797>.**
**An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.**

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**Pharmacy Name:** TOWN TOTAL COMPOUNDING CENTERS, LLC

**Pharmacy Address:** 415 CROSSWAYS PARK DRIVE, SUITE B, WOODBURY, NY 11797

**NABP Facility e-Profile ID:** 824605

**VPP Inspection Date:** 6/3/2021

## Facility Response to Verified Pharmacy Program® (VPP®) Inspection

| Type of Response (Choose from Drop Down) | VPP Inspection Report Page No. | VPP Inspection Report Item No. | Facility Response/Corrective Action/Comments | Estimated Date of Completion for Corrective Action Taken | Attachment Included (Y/N) | Title of Document (Must be indicated at top of document attachment) |
|---|---|---|---|---|---|---|
| Clarification or Further Explanation | 12 | 47.02 | Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase.*<br>The answer to this is NO, we feel this was a transcription error. Especially since there was nothing listed that was purchased from another pharmacy. | Current | N | |
| Clarification or Further Explanation | 40 | 8.03 | If extended BUDs are used, is further testing being performed to justify the use of extended BUDs?<br>Every batch is sent out for a USP <71> sterility test. Every batch for an injection is sent for a potency test. Every other batch for an ophthalmic is sent out for a potency test. | Current | N | |
| Clarification or Further Explanation | 42 | 19.00 | Does the pharmacy perform any testing in-house (not sent to an outside lab)?<br>The answer to this is NO. We perform glove finger tip testing, surface sampling, air sampling. But if any colonies form on the plates, they are sent to the outside lab for testing of the colonies identification. | Current | N | |
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This VPP inspection response and documentation has been provided directly by the pharmacy in response to its VPP inspection. The content of this response has not been verified or modified by NABP at this point in time, except to check for completeness of any attachments provided.

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| Clarification or Further Explanation | 42 | 19.00 | Does the pharmacy perform any testing in-house (not sent to an outside lab)?<br>The answer to this is NO. We perform glove finger tip testing, surface sampling, air sampling. But if any colonies form on the plates, they are sent to the outside lab for testing of the colonies identification. | Current | N | |
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# 8D

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Pharmacy Application

## Non-Refundable $500.00 Fee

Rev (8/02/2022)

| Facility Location | Application Type (check all applicable) | Pharmacy Type (check all applicable) | Services the Pharmacy will Provide (check all applicable) |
|---|---|---|---|
| ☐ Nevada | ☒ New Pharmacy | ☒ Retail/Community | ☒ Retail/Community |
| ☒ Out-of-State | ☐ Ownership Change* | ☐ Hospital (# beds _____) | ☒ Non-sterile Compounding |
| | ☐ Location Change * | ☐ Internet | ☒ Sterile Compounding |
| | ☐ Name Change* | ☐ Nuclear | ☐ Mail-Order Service |
| | | ☐ Other: | ☐ Off-site Cognitive Services |
| | * If making a change, provide license #: | | ☐ Long Term Care |
| | | | ☐ Hospital |
| | PH_____ | | ☐ Other: |

| Days of Operation | | Ownership Type (check applicable box) |
|---|---|---|
| ☒ Monday | ☒ Friday | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12) |
| ☒ Tuesday | ☐ Saturday | ☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12) |
| ☒ Wednesday | ☐ Sunday | ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12) |
| ☒ Thursday | ☐ Holidays | ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12) |

### Section 1: General Information

Pharmacy Name: WP Pharma Labs, Inc.

Physical Address: 4001 McEwen Ste 110

City: Dallas State: TX Zip: 75244

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 469-722-4500 Toll Free # (NAC 639.708, NRS 639.23286): 800-441-0048

Fax: 800-441-0048 Contact Email: regulatoryaffairs@wppharmalabs.com

Website: wppharmalabs.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Jerry Lance May

Supervising/Managing Pharmacist NV Pharmacist Registration #: 22115

**Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services In/Into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)**

| | |
|---|---|
| Name: Jerry Lance May | NV Pharmacist Registration #: 22115 |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |

| Section 3: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✔ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction? | | ✔ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry? | | ✔ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✔ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✔ |

**If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.**

**Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)**

| | | |
|---|---|---|
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

## Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

## Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Texas

Parent Company (if any): _____

Corporation/Organization Name: WP Pharma Labs, Inc.

Mailing Address: 4001 McEwen Suite 110

City: Dallas State: TX Zip: 75244

Telephone: 469-722-4500 Email: info@wppharmalabs.com

Contact Person Name: Faiez Usman

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

## Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

## Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

**Section 9: Statement of Responsibility- MUST BE COMPLETED by an Authorized Person (NAC 639.945)**

## Statement of Responsibility

1. I am the Faiez Usman, President (title) for WP Pharma Labs, Inc. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Faiez Usman, President

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

2/3/23

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Faiez Usman, President

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

2/6/23
Date

| Board Use Only | Date Received: 2.21.23 | Amount: 500.00 CC |
|---|---|---|

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

### Section 1: General Information

Pharmacy Name: WP Pharma Labs, Inc.

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 4001 McEwen Ste. 110

City: Dallas State: TX Zip: 75244

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 469-722-4500 Toll Free # (NAC 639.708, NRS 639.23286): 800-441-0048

Fax: 800-715-6589 Contact Email: regulatoryaffairs@wppharmalabs.com

Website: WPPharmalabs.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Kim Hiddessen

Supervising/Managing Pharmacist NV Pharmacist Registration #: Jerry Lance May #22115

Name of Person with direct knowledge of compounding procedures: Kim Hiddessen

Email of Person with direct knowledge of compounding procedures: khiddessen@wppharmalabs.com

Telephone of Person with direct knowledge of compounding procedures: 469-722-4500

**Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)**

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☐ Low ☒ Medium ☒ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☒ Yes ☐ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
Testosterone Cypionate, Testosterone Enanthate, Testosterone Propionate, Nandrolone, Anastrozole, DHEA, Levocarnitine, Glutamine, Arginine, Leucine, Isoleucine, Valine, Ornithine, Lysine, Methionine, Inositol, Choline Chloride, Vitamin D3, Chromium Picolinate, Methylcobalamin, Phenylephrine, Papaverine, Phentolamine, Alprostadil, Atropine, ABP-7, AOD-9604, ARA-290, BPC-157, CJC-1295, Delta Sleep Inducing Peptide, Epithalon, GHK-Cu, Gonadorelin, IGF-1, Ipamorelin, Kisspeptin, LL-37, Melanotan II, Met-Enkephalin, MOTs-C, NAD+, PEG-MGF, PT-141, Semax, Semaglutide, Sermorelin, Terzepatide, Thymulin.

4. Will you be utilizing beyond use dates in excess of USP-797? ☒ Yes ☐ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:
The following testing protocol is followed for products to received extended BUD's -
Container closure integrity testing - Day 0 and at end of test period (e.g. Day 90 or Day 180)
Sterility and Endotoxin testing - Day 0 and at end of test period (e.g. Day 90 or Day 180)
Potency testing - Day 0 and (at minimum) end of test period - generally tested every 30 days during study to track any decline in potency in storage.

These studies are transitioning to incorporate stability-indicating-assay tests this year to comply with the updated USP <797> chapter and maximum beyond use dates will conform the maximums given in the chapter.

6. What laboratory performs this additional testing?
Name: ARL Bio Pharma
Address: 840 Research Parkway, Ste. 546
City: Oklahoma City State: OK Zip: 73104
Telephone: 800-393-1595

7. What is your procedure for visual inspection of compounded sterile products?
Finished sterile products are inspected by a Quality Control technician and a Sterile Compounding Pharmacist in a light box with both white and black backgrounds to detect particles present in the solution and to inspect for any flaws in the vial or closure. Each batch is inspected twice - by QC and by a Pharmacist - before release.

8. How often do you perform glove fingertip and medial fill testing?

Glove fingertip testing is performed at the completion of every sterile compounded batch. Gowning validation and media fill testing is performed semi-annually for sterile compounding staff.

9. What is your policy if an employee fails a glove fingertip or media-fill test?

Employee will not be permitted to enter the ISO 7 Buffer Area until gowning validation has passed. If an alert limit is observed on a end-of-production batch plate, the entire batch will be destroyed. If a media fill test is failed, the employee will not be permitted to perform any duties related to sterile compounding until a media fill test is passed.

10. Describe your initial and annual training program for all personnel performing sterile compounding:

Personnel must attend a professional sterile compounding training course before being allowed to begin on-the-job training. Personnel must then complete a computer-based in-house didactic sterile compounding training course. Gowning validation must be performed three times consecutively with no failures before personnel can enter the clean room during compounding. Personnel are trained in cleaning and decontamination of the clean room suite and the process of disinfection of materials to be brought into the clean room suite prior to being allowed to commence a media fill test. A media fill test conducted under the most challenging conditions must be completed prior to being involved in the compounding process - whether as compounder or as support. These are repeated semi-annually. Any personnel responsible for mixing sterile compounds must pass a finished product assay (four ingredients are assayed) test to establish their ability to mix products to the required specifications.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Interior surfaces of ISO 5 primary engineering controls and exterior surfaces in ISO 7 Buffer Area are cleaned with sporicidal disinfectant (Spor-Klenz) at the beginning of each day upon which sterile compounding occurs. The ISO 5 work surfaces are cleaned after each product compounded with a deactivation/decontamination agent (Peridox RTU). The counters and floors of the ISO 7 secondary engineering controls (Buffer Area) are cleaned at the conclusion of compounding with sporicidal disinfectant (Spor-Klenz). The floors of each ISO-classified area are disinfected at the end of each day upon which they have been entered. Additionally, the walls and ceilings of all ISO-classified areas are disinfected on a monthly basis. A breach clean is performed following 1) entry to lab by non-certified personnel such as outside contractors, maintenance personnel or semi-annual certification personnel, 2) the completion of any repair or maintenance work which has the capacity to disrupt pressure differentials or generate viable or non-viable particles, 3)

12. Who performs the sterile compounding process at your facility?

Sterile compounding pharmacist - Kim Hiddessen
Sterile compounding technicians - Kristen Salinas, Evie Jerdee, Ruth Muentes, Jaime Rosa

13. Who is responsible and accountable for the sterile compounding process at your facility?

Kim Hiddessen - Pharmacist-in-Charge

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

Packaged in insulated mailing pouches with frozen cold packs. Volume of cold packs is increased during warmer months. Shipping speed (same-day courier, Next-Day Air or Second Day Air) is determined as required by outdoor weather conditions, storage requirements of the medication being shipped and the travel distance for the medication to arrive at the appropriate storage temperature.

**Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)**

1. What type of primary engineering controls will you be using in your facility?

ISO-5 Integrated Vertical Laminar Flow Zone

| | | |
|---|---|---|
| 2. Is your BSC or CACI vented 100% to the outside? | ☐ Yes | ■ No |
| 3. Do you have a negative pressure buffer room at your facility? | ☐ Yes | ■ No |
| 4. Will you be compounding with antineoplastic HDs or HD API? | ■ Yes | ☐ No |
| 5. If yes, are the drugs stored in an externally ventilated, negative pressure room? | ☐ Yes | ■ No |
| 6. Will you be utilizing a closed system transfer device? | ☐ Yes | ■ No |

7. If yes, list the name of the device:

8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

Guidance is provided with each prescription dispensed covering the following topics:
1. Proper storage of medications
2. Preventing contamination of sterile medications
3. Proper disposal of expired and unused medications
4. Proper disposal of unused, expired or discontinued injectable medications
5. Descriptions of physical appearances of products which indicate a potential problem with the medication - e.g. broken capsules, cloudy solutions, broken emulsions.
6. Explanation of drop-off sites and National Take Back Day for drug disposal.
7. Contact information for staff pharmacist for patients and providers to obtain additional information.

9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Gowning validation must be performed three times consecutively with no failures before personnel can enter the clean room during compounding.
Personnel are trained in cleaning and decontamination of the clean room suite and the process of disinfection of materials to be brought into the clean room suite prior to being allowed to commence a media fill test.
A media fill test conducted under the most challenging conditions must be completed prior to being involved in the compounding process - whether as compounder or as support. These are repeated semi-annually. Any personnel responsible for mixing sterile compounds must pass a finished product assay (four ingredients are assayed) test to establish their ability to mix products to the required specifications.
Specific to hazardous drugs, personnel are trained in the proper safe handling and containment of chemicals and materials. Specific gowning items (gloves, sleeves and masks) are utilized. Personnel are made aware of the risks involved with compounding and handling hazardous drugs and the importance of proper PPE to minimize the potential for exposure.

**Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)**

1. List the specific high risk sterile products that your facility compounds:

Testosterone Cypionate, Testosterone Enanthate, Testosterone Propionate, Nandrolone, Anastrozole, DHEA, Levocarnitine, Glutamine, Arginine, Leucine, Isoleucine, Valine, Ornithine, Lysine, Methionine, Inositol, Choline Chloride, Vitamin D3, Chromium Picolinate, Methylcobalamin, Phenylephrine, Papaverine, Phentolamine, Alprostadil, Atropine, ABP-7, AOD-9604, ARA-290, BPC-157, CJC-1295, Delta Sleep Inducing Peptide, Epithalon, GHK-Cu, Gonadorelin, IGF-1, Ipamorelin, Kisspeptin, LL-37, Melanotan II, Met-Enkephalin, MOTs-C, NAD+, PEG-MGF, PT-141, Semax, Semaglutide, Sermorelin, Terzepatide, Thymulin.

2. What sterilization methods are utilized at your facility?

Sterilization is achieved by 0.2 micron filtration in an ISO 5 environment using aseptic technique and sterile instruments.

3. Does your facility utilize biological indicators? ☑ Yes ☐ No

4. If yes, describe how they are utilized:

Biological indicators and endotoxin challenge vials are used for initial performance qualification and routine of the autoclaves and depyrogenation oven. Dry heat indicators and steam indicators are used to validate every sterilization cycle.

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Matthew Watkins
Name of Person who Completed the Form

Quality Assurance Supervisor
Title

Signature (copies or stamps not accepted)

16 Feb 2023
Date

| Board Use Only | Date Received:_____ Date Approved:_____ Approved By:_____ |
|---|---|




WP Pharma Labs, Inc
4001 McEwen Ste, 110
Dallas, TX 75244

Faiez Usman-President
[redacted] Colonnade Drive
Irving, TX 75039

Phone [redacted]

SS# [redacted]

DOB [redacted]

# Nevada State Board Of Pharmacy

(Licensee mailing address for window envelope)

THIS STUB IS YOUR RECEIPT

Jerry L. May

Date: 04/04/2022
Amount:
License #: 22115

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Pharmacist
Effective Date:04/04/2022
Expires:10/31/2023

Jerry L. May

License #
22115
Active

IDENTIFICATION ONLY
DOES NOT MEET POSTING REQUIREMENTS

(License mail trim ID Card to fit your wallet

Jerry L. May

Cut Here

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

# Office of the Secretary of State

## Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate of Formation for WP Pharma Labs, Inc. (file number 803300056), a Domestic For-Profit Corporation, was filed in this office on April 24, 2019.

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on January 18, 2023.

Jane Nelson
Secretary of State

# TEXAS STATE BOARD OF PHARMACY

| | |
|---|---|
| **Re:** | WP Pharma Labs |
| **Address:** | 4001 McEwen Road, Suite 110<br>Dallas, Texas 75244 |
| **License No.:** | 33003 |
| **Date Issued:** | November 21, 2019 |
| **Licensure Status:** | Active |
| **Expiration Date:** | November 30, 2023 |
| **Type of Pharmacy:** | Community Sterile Compounding |
| **Prior Disciplinary Orders**: | No |

The Texas State Board of Pharmacy maintains records regarding licensure and disciplinary action against a licensee. WP Pharma Labs (Texas Pharmacy License #33003) has not been subject to disciplinary action by the Texas State Board of Pharmacy.

Form Completed by:

Eamon D. Briggs

Eamon D. Briggs
Assistant General Counsel
Texas State Board of Pharmacy

April 25, 2022
Date

The Texas Department of State Health Services, Drugs and Medical Devices Division, Wholesaler Registration, 1100 W. 49th Street, Austin, TX 78756, is responsible for issuing registrations to wholesale drug distributors and drug manufacturers in Texas.

WP PHARMA LABS, INC
4001 MCEWEN RD STE 110
DALLAS, TX 75244-5388

10004368 2/002445-1/1-0

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| FW8979520 | 05-31-2025 | $888 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N, 3,3N,4,5 | RETAIL PHARMACY | 04-11-2022 |

WP PHARMA LABS, INC
4001 MCEWEN RD STE 110
DALLAS, TX 75244-5388

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| FW8979520 | 05-31-2025 | $888 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
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| 2,2N, 3,3N,4,5 | RETAIL PHARMACY | 04-11-2022 |

WP PHARMA LABS, INC
4001 MCEWEN RD STE 110
DALLAS, TX 75244-5388

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THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

This certifies that the pharmacy named below is hereby licensed to operate as a Class **AS** pharmacy.

License No. **33003** Expiration Date: **11/30/2023**

Balances: **5**

**WP PHARMA LABS**
**4001 MCEWEN RD STE 110**
**DALLAS TX 75244**

**Allison Vordenbaumen Benz, R.Ph., M.S.**
**Executive Director/Secretary**

**MUST BE DISPLAYED IN FULL PUBLIC VIEW**

# TEXAS STATE BOARD OF PHARMACY

## Texas Pharmacy License # 33003

## WP PHARMA LABS

### License Information

**License Status** Active
**License #** 33003
**Expiration Date** 11/30/2023
**Date License Issued** 11/21/2019

### Address

4001 MCEWEN RD STE 110
DALLAS, TX 75244
**County** DALLAS
**Phone** (800) 441-0048

### Pharmacy Details

**Prior Disciplinary Orders*** No

* Information relating to disciplinary orders is current as of 30 days prior to this date. Please note that disciplinary orders entered more than 10 years ago are not available online. A written request for information regarding prior disciplinary orders may be submitted to the office of the Texas State Board of Pharmacy. Any disciplinary orders entered pursuant to Chapter 564 of the Texas Pharmacy Act are confidential and not subject to public disclosure.

**Class of Pharmacy**
Community Sterile Compounding
**Type of Ownership** Corporation
**Type of Pharmacy** Community Independent
**# of Hospital beds**

### Employment Information

**Pharmacist in Charge**
HIDDESSEN, KIM M

### Pharmacy Profile ¥

| | |
|---|---|
| **Accessible to disabled persons?** | No |
| **Participates in the Texas Medicaid program?** | No |
| **Translating services (Listed Below If Available)** | |

¥ Please note: The data regarding accessibility, translating services, and insurance participation is self-reported by the license holder and no warranty regarding the information is created. Therefore, neither the State of Texas nor the licensing agency accept any legal liability or responsibility or may be held liable or responsible for the accuracy, completeness, timeliness, or usefulness of this information. Should you have any concern as to the accuracy of the data in this system, please contact the license holder or facility for clarification.

### Remedial Plans and Inspection Reports

- 1027047 33003 WPPHARMALABS 2019-11 11-2024.pdf
- 1027047 33003 WPPHARMALABS 2020-08 08-2025.pdf
- 1027047 33003 WPPHARMALABS 2021-11 11-2026.pdf

Remedial Plans and/or Inspection Reports (if any) are shown above and subject to removal at the end of the 5th fiscal year after the Board enters the plan.

### Services Provided

| | |
|---|---|
| **Nuclear** | No |
| **Out-Patient Prescriptions** | No |
| **Ship Prescription Out of State** | No |
| **Class D (Expanded Formulary)** | No |

| | |
|---|---|
| **Class D (Alternative Visit Schedule)** | No |
| **Compounding Sterile-Risk Level Low** | Yes |
| **Compounding Sterile-Risk Level Med** | Yes |
| **Compounding Sterile-Risk Level High** | Yes |
| **Compounding Non-Sterile** | Yes |
| **24 Hour Service** | No |
| **Closed Door** | Yes |
| **Compounding, Office Use** | No |
| **Home Delivery** | No |
| **Infusion** | No |
| **Pharmacist Administered Immunizations** | No |
| **Veterinary Prescriptions** | No |
| **In-Patient Medication Orders** | No |
| **Out-Patient Surgery** | No |
| **Rural Hospital** | No |
| **Tech Check Tech** | No |
| **503b Outsourcing Facility** | No |
| **Other Services** | No |

Texas Pharmacist Employment Information

| Pharmacist Name | License # | Registr. Date | Expir. Date | Emp. Status | License Status |
|---|---|---|---|---|---|
| ABRAHAM, SHAHBAAZ | 67867 | 10/29/2020 | 06/30/2024 | Staff | Active |
| HIDDESSEN, KIM M. | 56009 | 11/24/2014 | 12/31/2024 | PIC | Active |
| MAY, JERRY LANCE | 31737 | 04/27/1990 | 03/31/2023 | Staff | Active |

Page 1 of 1 20 View 1 - 3 of 3

Texas Registered Technicians/Trainees Employment Information

| Technician/Trainee Name | License # | Registr. Date | Expir. Date | Emp. Status | Reg. Status |
|---|---|---|---|---|---|
| AQUINO, RODALENE CASTRO | 285625 | 07/19/2018 | 01/31/2025 | Staff | Active |
| BARRERA FLORES, JESSICA | 252747 | 02/25/2016 | 07/31/2023 | Staff | Active |
| CROCIATA, GIANNA MARIE | 317876 | 02/09/2021 | 01/31/2024 | Staff | Active |
| DUNCAN, CHEREE R | 307502 | 04/24/2020 | 12/31/2023 | Staff | Active |
| FLORES, JUANA | 147270 | 05/04/2007 | 08/31/2023 | Staff | Active |
| JERDEE, EVIE L | 172886 | 03/30/2011 | 07/31/2023 | Staff | Active |
| MACKEY, SAMARA | 348849 | 12/08/2022 | 12/31/2024 | Staff | Active |
| MUENTES, RUTH ESTHER | 182078 | 03/09/2011 | 05/31/2023 | Staff | Active |
| MYERS, KELSEY ALANAH | 233168 | 08/06/2014 | 06/30/2024 | Staff | Active |
| ROSA, JAIME JOEL | 255662 | 05/06/2016 | 09/30/2024 | Staff | Active |
| SALINAS, KRISTEN NICOLE | 263152 | 11/08/2016 | 08/31/2023 | Staff | Active |

Page 1 of 1 20 View 1 - 11 of 11

Texas Remote Pharmacy Information

| Remote Pharmacy Name | Registr. # | Address | City | State | Zipcode |
|---|---|---|---|---|---|

Page 0 of 0 20 No records to view

Texas Pharmacy Owner Information

| Owner Name | Owner Title | Address | City | State | Zipcode |
|---|---|---|---|---|---|
| WP PHARMA LABS INC | OWNER | 701 BRAZOS ST STE 720, | AUSTIN | TX | 78701 |
| USMAN, FAIEZ HAROON | OFFICER | , | | | |

Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-500
Austin, TX 78701
512-305-8000

# Notice of Inspection

## Facility Information

**Name:** *WP PHARMA LABS*
**License Number:** *33003*
**Address:** *4001 MCEWEN RD STE 110, DALLAS, TX 75244*
**Phone:** *(800) 441-0048*
**Email:**
**Class of License:** *AS*
**License Expiration:** *11/30/2023*
**DEA #:** *FW8979520*
**DEA Expiration:** *05/31/2022*

## Inspection Information

**Type:** *Compliance*
**Purpose:** *Licensee Request*
**Date:** *11/09/2021*
**Arrival Time:** *9:15 AM*

## Acknowledgment

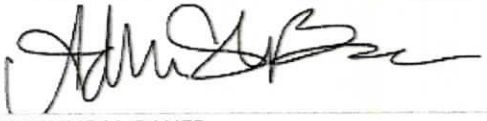
This is to acknowledge that Texas State Board of Pharmacy Agent has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

1. I have read the Notice of Inspection and understand its contents and purpose;
2. I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
3. I have had the purpose of the entry into the above-described facility by the Boards agent stated to me; and
4. I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.



*KIM HIDDESSEN, PIC, 56009*

## Witnesses



*ADRIENNE M. BAUER*

Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-500
Austin, TX 78701
512-305-8000

# Inspection Report

## Facility Information

Name: *WP PHARMA LABS* License Number: *33003*
Class of License: *AS*

## Inspection Information

Type: *Compliance* Purpose: *Licensee Request*
Date: *11/09/2021* Arrival Time: *9:15 AM* Departure Time: *5:00 PM*
Action Taken: *Inspection*

## Licenses/Registration

| | |
|---|---|
| Verify personnel have active licenses & address with PIC/RPh if necessary | *Satisfactory* |
| 01. Required licenses posted | *Satisfactory* |
| 09. Active licenses/certifications | *Satisfactory* |
| 62. No aiding and abetting | *Satisfactory* |
| 65. Proper registration procedures | *Satisfactory* |
| 79. Identification badges | *Satisfactory* |

## Inventory Records

| | |
|---|---|
| 15. Change of PIC inventory | *Not Applicable* |
| 17. Meets inventory requirements | *Satisfactory* |
| 59. Proper drug destruction | *Satisfactory* |
| 68. Change of ownership controlled substance inventory | *Not Applicable* |
| 69. Annual controlled substance inventory | *Satisfactory* |

Comment

*Annual controlled substance inventory completed on: 12/31/2020 O*

## Notifications

| | |
|---|---|
| 31. Closed pharmacy (Is pharmacy engaged in the business described in application for licensure?) | *Satisfactory* |
| 34. Notifications | *Satisfactory* |
| 76. PIC (Does the pharmacy have a pharmacist-in-charge?) | *Satisfactory* |

WP PHARMA LABS 33003

## Environment/Equipment/Security

| | |
|---|---|
| 03. Orderly/Clean | Satisfactory |
| 04. Balance inspection | Satisfactory |
| 05. Equipment Inspection | Satisfactory |
| 07. Security | Satisfactory |
| 08. Environment | Satisfactory |
| 48. Drugs (procurement, temperature, security, out-of-date, samples) | Satisfactory |
| 90. TSBP complaint notification | Satisfactory |

## Controlled Substances

| | |
|---|---|
| 10. Prescriptions separated | Satisfactory |
| 24. Theft/Loss | Satisfactory |
| Comment | |
| *No theft or loss has occurred.* | |
| 26. Controlled substance prescription compliance | Satisfactory |
| Comment | |
| *Ensure faxed controlled substance prescriptions bear the prescriber's manual signature.* | |
| 30. Controlled substance invoices dated/initialed by pharmacist | Satisfactory |
| 35. Controlled substance invoices separated | Satisfactory |
| 46. Drug distribution | Satisfactory |
| 53. Possession of controlled substances | Satisfactory |
| 57. Corresponding responsibility (Does the pharmacist exercise sound professional judgment with respect to the accuracy or authenticity of a prescription drug order?) | Satisfactory |

## Labeling/Prepackaging

| | |
|---|---|
| 32. Prescription label (Is prescription label complete?) | Satisfactory |
| 45. Proper dispensing/labeling | Satisfactory |
| 54. Proper prepackaging procedures | Not Applicable |

## Library

| | |
|---|---|
| 06. Required Library | Satisfactory |

WP PHARMA LABS 33003

## Training

**60. Documentation of required training** *Satisfactory*

297.6(e).

Pharmacy technician and pharmacy technician trainee training shall be outlined in a training manual. Such training manual shall, at a minimum, contain the following:
(1) written procedures and guidelines for the use and supervision of pharmacy technicians and pharmacy technician trainees. Such procedures and guidelines shall:
(A) specify the manner in which the pharmacist responsible for the supervision of pharmacy technicians and pharmacy technician trainees will supervise such personnel and verify the accuracy and completeness of all acts, tasks, and functions performed by such personnel; and
(B) specify duties which may and may not be performed by pharmacy technicians and pharmacy technician trainees; and
(2) instruction in the following areas and any additional areas appropriate to the duties of pharmacy technicians and pharmacy technician trainees in the pharmacy:
(A) Orientation;
(B) Job descriptions;
(C) Communication techniques;
(D) Laws and rules;
(E) Security and safety;
(F) Prescription drugs:
(i) Basic pharmaceutical nomenclature;
(ii) Dosage forms;
(G) Drug orders:
(i) Prescribers;
(ii) Directions for use;
(iii) Commonly-used abbreviations and symbols;
(iv) Number of dosage units;
(v) Strengths and systems of measurement;
(vi) Routes of administration;
(vii) Frequency of administration; and
(viii) Interpreting directions for use;
(H) Drug order preparation:
(i) Creating or updating patient medication records;
(ii) Entering drug order information into the computer or typing the label in a manual system;
(iii) Selecting the correct stock bottle;
(iv) Accurately counting or pouring the appropriate quantity of drug product;
(v) Selecting the proper container;
(vi) Affixing the prescription label;
(vii) Affixing auxiliary labels, if indicated; and
(viii) Preparing the finished product for inspection and final check by pharmacists;
(I) Other functions;
(J) Drug product prepackaging;
(K) Written policy and guidelines for use of and supervision of pharmacy technicians and pharmacy technician trainees; and
(L) Confidential patient medication records.

**Comment**

*Advised to maintain a complete Technician Training Manual with all required topics. Ensure documentation of training bears signature of technician and PIC.*

**61. Supervision of supportive personnel** *Satisfactory*

## Patient/Computer/Dispensing Records

**18. Records available** *Satisfactory*

**21. Data processing records complete** *Satisfactory*

**22. Data processing system compliance** *Satisfactory*

WP PHARMA LABS 33003

## Patient/Computer/Dispensing Records *(continued)*

| | |
|---|---|
| **25. Prescriptions (complete, retrievable, auto-refills, accelerated refills)** | *Satisfactory* |
| **37. Legal dispensing (Are valid prescriptions being dispensed by a pharmacist?)** | *Satisfactory* |
| **56. Prescription transfers** | *Satisfactory* |
| **67. Written drug information provided** | *Satisfactory* |
| **80. Patient counseling** | *Satisfactory* |
| **82. Patient Medication Records** | *Satisfactory* |

291.34(c)(3).

Patient medication records. The pharmacist-in-charge shall assure that a reasonable effort is made to obtain and record in the patient medication record at least the following information:
(A) full name of the patient for whom the drug is prescribed;
(B) address and telephone number of the patient;
(C) patient's age or date of birth;
(D) patient's gender;
(E) any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs currently being used by the patient which may relate to prospective drug regimen review;
(F) pharmacist's comments relevant to the individual's drug therapy, including any other information unique to the specific patient or drug; and
(G) a list of all prescription drug orders dispensed (new and refill) to the patient by the pharmacy during the last two years. Such lists shall contain the following information:
(i) date dispensed;
(ii) name, strength, and quantity of the drug dispensed;
(iii) prescribing practitioner's name;
(iv) unique identification number of the prescription; and
(v) name or initials of the dispensing pharmacists.

**Comment**

*Advised to make a reasonable effort to complete PMR with all required information.*

| | |
|---|---|
| **84. Drug regimen review** | *Satisfactory* |
| **86. Absence of pharmacist records** | *Not Applicable* |

## Policies & Procedures

| | |
|---|---|
| **70. Required policies & procedures** | *Satisfactory* |
| **92. Automated dispensing policy & procedures** | *Not Applicable* |

## Non-Sterile Compounding

| | |
|---|---|
| **38. Area for non-sterile compounding** | *Satisfactory* |
| **43. Records for non-sterile compounding** | ***Unsatisfactory*** |

**Comment**

*Review 291.131(d)(1)(D) regarding compounding commercially available products for patients with a specific medical need. Maintain documentation from prescriber.*

291.131(d)(8).

Operational Standards.(8) Compounding process. (A) All significant procedures performed in the compounding area shall be covered by written SOPs designed to ensure accountability, accuracy, quality, safety, and uniformity in the compounding

**43. Records for non-sterile compounding *(continued)*** ***Unsatisfactory***

process. At a minimum, SOPs shall be developed for: (i) the facility; (ii) equipment; (iii) personnel; (iv) preparation evaluation; (v) quality assurance; (vi) preparation recall; (vii) packaging; and (viii) storage of compounded preparations. (B) Any compounded preparation with an official monograph in the USP/NF shall be compounded, labeled, and packaged in conformity with the USP/NF monograph for the drug. (C) Any person with an apparent illness or open lesion that may adversely affect the safety or quality of a drug product being compounded shall be excluded from direct contact with components, drug product containers, closures, any materials involved in the compounding process, and drug products until the condition is corrected. (D) Personnel engaged in the compounding of drug preparations shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as coats/jackets, aprons, hair nets, gowns, hand or arm coverings, or masks shall be worn as necessary to protect personnel from chemical exposure and drug preparations from contamination. (E) At each step of the compounding process, the pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate to conform to the formula being prepared.

**Warning Notice** **Due Date for Completed Correction:** *12/09/2021*

*Failure to hand complete non-sterile compounding SOPs, including preparation recall procedure. Correct/resolve deficiency by date noted. Correct/resolve deficiency by date noted.*

## Compounded Dosage Forms

| | |
|---|---|
| Allergen extracts | *No* |
| Parenteral solutions | *No* |
| Parenteral suspensions | *No* |
| Preservative-free parenterals | *No* |
| Ophthalmic preparations | *No* |
| Oral or nasal inhalation preparations (not topical spray) | *No* |
| Bath or soaks for live organs/tissues | *No* |
| Irrigations for wounds or body cavities | *No* |
| Any other sterile preparations (implants, pellets, etc) [list] | *Yes* |

**Comment**

*Subcutaneous and IM Injectable preparations*

| | |
|---|---|
| Investigational drugs | *No* |
| Blood products or other biological materials (wound care, autologous, eye drops, etc) | *No* |
| Any compounds using federally controlled substances Schedule I-V (list and percentage) | *Yes* |

**Comment**

*Testosterone*
*7.5%*

*Nandrolone*
*1%*

*Oxandrolone*

**Comment (continued)**

*Phentermine*
*1%*

| | |
|---|---|
| Does the pharmacy use lyophilizer? | *Yes* |

## Environment (Sterile)

| | |
|---|---|
| S109. Is the cleanroom clean and free of objects that shed particles? | *Satisfactory* |
| S110. Is the cleanroom used only for sterile preparations? | *Satisfactory* |
| S119. Does the cleanroom contain only appropriate supplies? | *Satisfactory* |
| S101. Does the ante-area provide at least ISO Class 8 air quality under dynamic conditions? | *Satisfactory* |
| S115. Does the ante-area contain a hands-free sink with hot and cold running water? | *Satisfactory* |
| S102. Does the buffer area provide at least ISO Class 7 air quality under dynamic conditions? | *Satisfactory* |
| S106. Is the buffer area free from sources of water (e.g., sink, floor drains)? | *Satisfactory* |
| S108. Is there hands-free access to the buffer area? | *Satisfactory* |
| S113. Are floors, walls, ceilings & fixtures smooth, impervious and free from cracks & crevices? | *Satisfactory* |
| S112. Does the floor covering enable regular disinfection? | *Satisfactory* |
| S118. Are supplies stored above the floor to permit adequate floor cleaning? | *Satisfactory* |
| S127. Does the clean room have a pressure gauge or velocity meter to monitor pressure differential between buffer area and ante-area and between the ante-area and the general environment? Is the pressure differential at least 0.02" wc? | *Satisfactory* |
| S116. Are temperature and humidity monitored, documented and within the required range? | *Satisfactory* |
| S167. Is there a thermometer available for the cleanroom and refrigerator(s)? | *Satisfactory* |

## Primary Engineering Control (PECs) Device

| | |
|---|---|
| S126. Is the laminar air flow hood located in a buffer area that has a minimum differential positive pressure of 0.02" wc? | *Satisfactory* |
| S121. Is the PEC able to maintain at least ISO Class 5 conditions while compounding sterile preparations? | *Satisfactory* |
| S246. Are hazardous drugs prepared in a Class II/III vertical flow BSC or CACI located in an ISO Class 7 area physically separated from other areas? | *Satisfactory* |

**Comment**

*Pharmacy prepared a CSP batch containing mitomycin in ISO 5 laminar airflow workbench. Product was not dispensed. PIC states that the product will no longer be compounded.*

WP PHARMA LABS 33003

## Primary Engineering Control (PECs) Device *(continued)*

| | |
|---|---|
| S247. Does the area where the BSC or CACI is located have not less than 0.01" wc negative pressure adjacent to the positive pressure ISO Class 7 area? | *Not Applicable* |
| S105. Does the CAI or CACI provide unidirectional airflow? | *Not Applicable* |
| S104. If the CAI or CACI is used for high-risk sterile compounding, is it placed in an ISO Class 8 area? | *Not Applicable* |
| S122. If the CAI is not required to be placed in an ISO Class 7 area, does the pharmacy maintain documentation from the manufacturer? | *Not Applicable* |
| S124. Is the PEC certified by an independent contractor every 6 months and when relocated? | *Satisfactory* |
| S125. Are prefilters inspected periodically and replaced as needed? | *Not Applicable* |
| S128. Are differential pressures monitored and documented at least every work shift (at a minimum daily) or by a continuous recording device? | *Satisfactory* |

## Equipment and Supplies

| | |
|---|---|
| S174. Does the pharmacy have disposable needles, syringes, and other required or applicable supplies? | *Satisfactory* |
| S177. Does the pharmacy have lint-free towels or wipes? | *Satisfactory* |
| S180. Does the pharmacy have masks, caps, gowns with tight cuffs, shoes covers, and beard covers (if applicable)? | *Satisfactory* |
| S176. Does the pharmacy have handwashing agents with bactericidal action? | *Satisfactory* |
| S175. Does the pharmacy have disinfectant cleaning solutions and dedicated cleaning supplies? | *Satisfactory* |
| S179. Does the pharmacy have hazardous spill kits, if applicable? | *Not Applicable* |
| S171. Does the pharmacy have appropriate containers for needles and syringes? | *Satisfactory* |
| S170. Does the pharmacy have sterile isopropyl alcohol, sterile gloves, and waterless alcohol-based surgical hand scrub? | *Satisfactory* |
| S178. Does the pharmacy have appropriate filters and filtration equipment? | *Satisfactory* |
| S181. If an automated compounding device is used, does the pharmacy calibrate & verify the device for accuracy, and document at least daily? | *Not Applicable* |
| S172. Does the pharmacy have packaging or delivery containers to maintain proper storage conditions for sterile preparations? | *Satisfactory* |

## High Risk CSPs

| | |
|---|---|
| S103. If high-risk CSPs are compounded, does the buffer area provide physical separation from other compounding areas? | *Satisfactory* |
| S231. Is sterility testing performed if CSPs are prepared in groups > 25, or | *Satisfactory* |

## High Risk CSPs *(continued)*

| | |
|---|---|
| S232. If MDVs are prepared for multiple patients or when exposed > 12 hours at 2-8 degrees C before sterilized, or | *Not Applicable* |
| S233. If exposed > 6 hours at warmer than 8 degrees C before sterilized? | *Not Applicable* |
| S237. Are all non-sterile measuring, mixing, and purifying devices rinsed thoroughly with pyrogen-free or depyrogenated sterile water, and then thoroughly drained or dried immediately before use for high-risk sterile compounding? | *Satisfactory* |
| S238. Are all high-risk sterile solutions subjected to terminal sterilization prefiltered using no larger than a 1.2-micron filter to remove particulate matter? Is sterilization by filtration performed with a sterile 0.2 – 0.22 micrometer pore size filter within an ISO Class 5 environment or better? | *Satisfactory* |
| S165. Are filter integrity tests being performed and documented (e.g., bubble point test)? | *Satisfactory* |
| S239. Are pre-sterilization procedures (weighing and mixing) completed in an ISO Class 8 environment or better? | *Satisfactory* |

## Sterile Library

| | |
|---|---|
| S154. Does the pharmacy have a reference on injectable drugs? | *Satisfactory* |

**Comment**

*Advised to have an updated reference on injectable drugs.*

| | |
|---|---|
| S155. Does the pharmacy have a specialty reference? | *Satisfactory* |
| S156. Does the pharmacy have all of the required (USP chapters 71, 85, 795, 797, 1163) and applicable USP chapters? | *Satisfactory* |

## Hazardous CSPs

| | |
|---|---|
| S242. Do personnel wear protective apparel at all times when hazardous drugs are handled? | *Not Applicable* |
| S243. Do personnel use appropriate safety and containment techniques when preparing hazardous CSPs? | *Not Applicable* |
| S244. Do personnel dispose of hazardous waste in compliance with local, state, and federal regulations? | *Not Applicable* |
| S245. Do personnel affix a proper label, including proper precautions inside and outside of the packaging? | *Not Applicable* |
| S248. Does the pharmacy have a pressure indicator that can be readily monitored for correct room pressurization? | *Not Applicable* |
| S249. Does the pharmacy meet the requirements for low volume preparation of hazardous drugs by using a device that provides two-tiers of containment (e.g., closed-system vial transfer device within a BSC)? | *Not Applicable* |
| S250. Are hazardous drugs stored separately from other inventory in a manner to prevent contamination and personnel exposure? | *Not Applicable* |

| | |
|---|---|
| | Satisfactory |
| | Satisfactory |
| | Satisfactory |
| WP PHARMA LABS | 33003 |

## Hazardous CSPs *(continued)*

| | |
|---|---|
| Does the pharmacy have a plan to comply with USP <800> by the implementation date? | *Not Applicable* |
| Are hazardous drugs stored separately in compliance with USP <800> (negative pressure at least -0.01" wc to adjacent areas and with at least 12 ACPH)? | *Not Applicable* |
| Is hazardous drug waste quarantined in a designated area? | *Yes* |
| Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)? | *Yes* |

## Personnel Cleansing, Garbing, Hand Hygiene

| | |
|---|---|
| S202. Does hand sanitizing and gowning occur in the ante-area (outside of the buffer area)? | *Satisfactory* |
| S180. Do compounding personnel don clean non-shedding gowns with sleeves that fit snugly around the wrists and enclose at the neck? Is the order of garbing appropriate (dirtiest to cleanest)? | *Satisfactory* |
| S194. Before entering the buffer area, do compounding personnel remove cosmetics? | *Satisfactory* |
| S195. Before entering the buffer area, do compounding personnel remove all hand, wrist, and other body jewelry/piercings? | *Satisfactory* |
| S196. Are natural nails kept neat and trim and no wearing of artificial nails or extenders? | *Satisfactory* |
| S200. Do compounding personnel remove debris from underneath fingernails using a nail cleaner under running warm water? | *Satisfactory* |
| S192. Are personnel with an apparent illness or open lesions compounding sterile preparations? | *Satisfactory* |
| S241. When compounding personnel temporarily exit the ISO Class 7 environment, are re-donning procedures properly followed? | *Satisfactory* |
| S201. Do compounding personnel engage in proper hand hygiene? | *Satisfactory* |
| S203. Do compounding personnel completely dry hands and forearms using lint-free disposable towels or hand dryer? | *Satisfactory* |
| S204. Is antiseptic hand cleansing performed using waterless alcohol-based surgical scrub once inside the buffer area and prior to donning sterile gloves? | *Satisfactory* |

**Comment**

*Advised to apply waterless alcohol-based surgical scrub on hands, use sterile IPA on gloves.*

| | |
|---|---|
| S206. Is sterile isopropyl alcohol applied to gloves throughout the day and when non-sterile surfaces are touched? | *Satisfactory* |

## Cleaning/Disinfection Procedures

| | |
|---|---|
| S182. Does the pharmacy have written procedures on the cleaning and disinfecting of the direct and contiguous compounding areas (e.g., beginning of shift, every 30 minutes, before each batch, spills)? | *Satisfactory* |
| S230. Is cleaning performed by trained personnel using approved agents (described in written SOPs)? | *Satisfactory* |
| S228. Are supplies & equipment that are removed from shipping cartons wiped with a disinfecting agent (e.g., sterile IPA)? | *Satisfactory* |
| S226. Are work surfaces and floors in the ante-area and buffer area cleaned and disinfected daily with dedicated supplies? | *Satisfactory* |
| S227. Are walls, ceilings and shelving in the ante-area and buffer area cleaned and disinfected at least monthly? | *Satisfactory* |
| S229. Does the pharmacy maintain documentation of cleaning procedures (i.e., date/time of cleaning, type of cleaning, name of individual who performed the cleaning)? | *Satisfactory* |

## Environmental Sampling

| | |
|---|---|
| S270. Is surface sampling conducted in all ISO classified areas on a periodic basis? | *Satisfactory* |
| S272. Is viable air sampling performed? | *Satisfactory* |
| S273. Is viable air sampling documented by properly trained individuals for all risk levels every 6 months? | *Satisfactory* |

**Comment**

*Advised to maintain documentation of training for individual performing viable air sampling.*

| | |
|---|---|
| S271. Are environmental sampling results evaluated and addressed (i.e., action levels followed)? | *Satisfactory* |

## Records of CSPs

| | |
|---|---|
| S252. Does the pharmacy maintain records relating to CSPs for a minimum of 2 years? | *Satisfactory* |
| S253. Do compounding records include the date and time of preparation of a CSP? | *Satisfactory* |

**Comment**

*Advised to ensure compounding records contain the time of preparation of the compounded sterile preparation.*

| | |
|---|---|
| S254. Do compounding records include the complete formula of a CSP? | *Satisfactory* |
| S257. Do compounding records include the quantities of materials used in a CSP? | *Satisfactory* |
| S255. Do compounding records include the signature or initials of who prepared a CSP? | *Satisfactory* |
| S256. Do compounding records include the signature or initials of who conducted the final check of a CSP? | *Satisfactory* |

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## Records of CSPs *(continued)*

**S258. Do compounding records include the container used and the number of units prepared for a CSP?** *Satisfactory*

**S259. Do compounding records include the criteria used to determine the beyond-use date of a CSP?** *Not Applicable*

**S260. Do compounding records include the documentation of performance of quality control procedures?** *Satisfactory*

**S261. Are master worksheets and preparation worksheets for batch compounding complete?** *Satisfactory*

**Comment**

*Advised to ensure master worksheets for batch compounding are complete with equipment and compounding instructions.*

**S262. Are master worksheets developed and approved by a pharmacist?** *Satisfactory*

## General Operational Requirements

**S166. Is a pharmacist available at all times (24/7)?** *Satisfactory*

**S187. Are written SOPs developed and implemented for all significant procedures in the compounding area to include at a minimum: the facility, equipment, personnel, preparation evaluation, quality assurance, preparation recall, packaging, and storage of CSPs?** *Satisfactory*

**S188. Does the pharmacy have all required written policies (e.g., pharmaceutical care services, sampling plan, recalls)?** ***Unsatisfactory***

291.133(g).

Recall Procedures.
(1) The pharmacy shall have written procedures for the recall of any compounded sterile preparation provided to a patient, to a practitioner for office use, or a pharmacy for administration. Written procedures shall include, but not be limited to the requirements as specified in paragraph (3) of this subsection.
(2) The pharmacy shall immediately initiate a recall of any sterile preparation compounded by the pharmacy upon identification of a potential or confirmed harm to a patient.
(3) In the event of a recall, the pharmacist-in-charge shall ensure that:
(A) each practitioner, facility, and/or pharmacy to which the preparation was distributed is notified, in writing, of the recall;
(B) each patient to whom the preparation was dispensed is notified, in writing, of the recall;
(C) the board is notified of the recall, in writing, not later than 24 hours after the recall is issued;
(D) if the preparation is distributed for office use, the Texas Department of State Health Services, Drugs and Medical Devices Group, is notified of the recall, in writing;
(E) the preparation is quarantined; and
(F) the pharmacy keeps a written record of the recall including all actions taken to notify all parties and steps taken to ensure corrective measures.
(4) If a pharmacy fails to initiate a recall, the board may require a pharmacy to initiate a recall if there is potential for or confirmed harm to a patient.
(5) A pharmacy that compounds sterile preparations shall notify the board immediately of any adverse effects reported to the pharmacy or that are known by the pharmacy to be potentially attributable to a sterile preparation compounded by the pharmacy.

**Warning Notice** **Due Date for Completed Correction:** *12/09/2021*

*Failure to ensure pharmacy has written policies for CSP recall as required. Correct/resolve deficiency by date noted.*

WP PHARMA LABS 33003

## General Operational Requirements *(continued)*

| | |
|---|---|
| S158. If the pharmacy compounds commercially available products, does the pharmacy document the need by verifying and monitoring a drug shortage list (including if the preparation is quarantined/not available once removed from the shortage list)? Or, | *Not Applicable* |
| S158. Does the pharmacy document the need for compounding commercially available products by individual patient needs determined by the prescribing practitioner (i.e, hypersensitivity to inactive ingredients or alternate dosage form)? | *Not Applicable* |
| S275. If the pharmacy dispenses prescriptions to patients in other states, does the pharmacy have proper licensure in those states? | *Satisfactory* |

## Office Use Compounding & Distribution of CSPs

| | |
|---|---|
| S163. Does the pharmacy have a written agreement with the prescriber that meets all requirements to distribute compounded sterile preparations to practitioners for office use? | *Satisfactory* |
| S162. If the pharmacy is distributing CSPs to another pharmacy, does the pharmacy meet the requirements for such distribution? | *Not Applicable* |
| Is the pharmacy registered with the FDA as an Outsourcing Facility (503B)? | *No* |

## Quality Control & Verification of Compounding Accuracy

| | |
|---|---|
| S207. Does a pharmacist review all compounding records for accuracy and perform the final check of a CSP? | *Satisfactory* |
| S185. Are periodic in-process checks for CSPs defined in written procedures and conducted as defined? | *Satisfactory* |
| S191. Are all drug components USP/NF grade substances manufactured in an FDA-registered facility? If USP/NF grade substances are not available, are the drug components of chemical grade in CP, AR, ACS, or Food Chemical Codex categories? | *Satisfactory* |
| S191. Is a Certificate of Analysis available for all components of the preparation if materials are not purchased through an FDA-registered facility? | *Not Applicable* |
| S191. Are any CSPs prepared by the pharmacy listed on the federal FDA list of drug products that are withdrawn or removed from the market for safety reasons? | *Not Applicable* |

## Veterinary Compounding

| | |
|---|---|
| Are APIs or other components labeled for veterinary use segregated or marked to prevent use for human compounding? | *Yes* |
| Does the pharmacy meet the same standards for animal compounding as human compounding? | *Yes* |
| Is the pharmacist knowledgeable or does the pharmacy have up-to-date references regarding species limits that can result in toxicity when compounding with particular drugs/excipients? | *Yes* |
| Does the pharmacy document if the animal is a pet or used for food? | *Yes* |

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## Veterinary Compounding *(continued)*

| | |
|---|---|
| Is the pharmacist familiar with, or does the pharmacy have the most up-to date references regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals? | *Not Applicable* |
| Does the pharmacy have a list of drugs and components that have been designated by state or federal authorities as prohibited ingredients in CSPs for food-producing animals? | *Not Applicable* |
| Is the pharmacist familiar with, or does the pharmacy have the most up-to-date reference regarding regulations for drug use in performance animals? | *Yes* |

## Label

| | |
|---|---|
| S209. Is the CSP properly labeled to include the generic name(s), and | *Satisfactory* |
| S210. For outpatient prescriptions, does the label include a statement that the CSP has been compounded by the pharmacy? | *Satisfactory* |
| S211. Does the label include a beyond-use date? | *Satisfactory* |
| S213. If the CSP is compounded as a batch, does the label contain a unique lot number assigned to the batch, and | *Satisfactory* |
| S214. Quantity, and | *Satisfactory* |
| S215. Appropriate ancillary instructions, such as storage or cautionary statements, and | *Satisfactory* |
| S216. Any device-specific instructions, if appropriate? | *Satisfactory* |
| S220. Are CSPs assigned a beyond-use date based on the specified labeling for the drug, appropriate literature sources, or direct testing? | *Satisfactory* |

**Comment**

*Advised to ensure compounded sterile preparations are assigned a beyond-used date in accordance with specified manufactures' product labeling, appropriate literature sources, or direct testing. Drug-specific and general stability documentation and literature should also be considered. The nature of the drug and its degradation mechanism, the container in which the CSP is packaged, the expected storage conditions, and the intended duration of therapy should be taken into consideration when assigning a beyond-use date.*

## Training & Competency Testing

| | |
|---|---|
| S129. Has each pharmacist completed the required education and training prior to engaging in sterile compounding? | *Satisfactory* |
| S130. Has each pharmacy technician completed the required education and training prior to engaging in sterile compounding? | *Satisfactory* |
| S142. Does the pharmacy maintain documentation to demonstrate that all compounding personnel have successfully passed initial competency evaluation/testing (e.g., media-fill testing, gloved fingertip/thumb testing)? Does the pharmacy have an on-the-job training program? | *Satisfactory* |

WP PHARMA LABS 33003

## Training & Competency Testing *(continued)*

S144. Does the pharmacy maintain documentation of on-going training and testing for all compounding personnel (e.g., observation of aseptic technique, media-fill testing, gloved fingertip/thumb testing, continuing education)? *Satisfactory*

## Signatures

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted.

- Items designated as "Refer to Legal" must be rectified immediately. In addition, the matter discovered during the inspection and deemed to be a serious violation by the inspector will be referred to the Legal Division for review and possible disciplinary action; and
- Items designated as "Warning Notice" must be corrected by the deadline noted to ensure compliance with the laws and rules governing the practice of pharmacy (Note: A "Warning Notice" is issued for a minor violation, and does not equate to disciplinary action).

*KIM HIDDESSEN, PIC, 56009*

*Adrienne M Bauer*

Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-500
Austin, TX 78701
512-305-8000

# Warning Notice of Violation(s) Requiring Correction

**Facility/Inspection Information**

**Name:** *WP PHARMA LABS* **License Number:** *33003*
**Class of License:** *AS*

Signatures

**Notice is hereby given that you are not in compliance with the following laws and rules governing the practice of pharmacy. Unless the conditions noted below are corrected, disciplinary action may be instituted against the pharmacy license and the license of the pharmacist-in-charge.**

**I hereby acknowledge that the laws and/or rules cited in the Warning Notice below have been explained to me by the Board of Pharmacy Officer/Inspector.**

*KIM HIDDESSEN, PIC, 56009*

11/09/2021
Date

## Warning Notice

1. **Rule/Law/Code:** 291.131(d)(8).

   **Explanation of Violation and Correction Needed:**
   *Failure to hand complete non-sterile compounding SOPs, including preparation recall procedure. Correct/resolve deficiency by date noted. Correct/resolve deficiency by date noted.*

   **Due Date for Completed Correction:** *12/09/2021*

2. **Rule/Law/Code:** 291.133(g).

   **Explanation of Violation and Correction Needed:**
   *Failure to ensure pharmacy has written policies for CSP recall as required. Correct/resolve deficiency by date noted.*

   **Due Date for Completed Correction:** *12/09/2021*

# TEXAS STATE BOARD OF PHARMACY

**Pharmacist in Charge Attestation:**

**I hereby attest the following statements are true and accurate (initial each statement below):**

KH I am the Pharmacist-in-Charge (PIC) of *WP PHARMA LABS*, pharmacy license number *33003*, and I ☑ was/ ☐ was not present during a Compliance Inspection conducted by a Texas State Board of Pharmacy Compliance Officer/Inspector on *11/09/2021*.

KH I received and reviewed the Notice of Inspection, Inspection Report, and Warning Notice (if applicable) issued by the Compliance Officer/Inspector.

KH I reviewed the document titled Texas State Board of Pharmacy "Red Flags" Checklist for Pharmacies YOU MIGHT BE A PILL MILL IF (on the attestation printout).

KH If applicable, the Warning Notice issued contains *2* deficiencies which may require corrections to resolve. I affirm that each of the deficiencies will be corrected by the date noted on the Warning Notice.

KH I was present and completed this Attestation during the Compliance Inspection.

If not completed during the Compliance Inspection, please mail, email, or fax this completed form to the Board office within 7 days of the date of the inspection:

Texas State Board of Pharmacy
Attn: Compliance Division
333 Guadalupe St. Suite 3-500
Austin. Texas 78701
Email: inspections@pharmacy.texas.gov
Fax: 512-305-8082

**Signed:** K Hiddessen

**Date:** *11/09/2021*

**Printed Name:** *KIM HIDDESSEN*

**License No.(if applicable):** *56009*

**Texas State Board of Pharmacy**
**"Red Flags" Checklist for Pharmacies**
**YOU MIGHT BE A PILL MILL IF...**

*Check all that apply:*

| | |
|---|---|
| | (1) Your pharmacy fills a discernable pattern of prescriptions for prescribers who write essentially the same prescriptions for numerous persons, indicating a lack of individual drug therapy |
| | (2) Your pharmacy operates with limited hours of operation or closes after a certain threshold of controlled substance prescriptions are dispensed, and has overall low prescription dispensing volume. |
| | (3) Prescriptions presented to the pharmacy are for controlled substances with popularity as street drugs, such as opiates, benzodiazepines, muscle relaxants, psychostimulants, and/or cough syrups, or any combination of these drugs. |
| | (4) The prescriptions for controlled substances contain nonspecific or no diagnoses. |
| | (5) The prescriptions are commonly for the highest strength of the drug and/or for large quantities. |
| | (6) Dangerous drugs or OTC products (such as multi-vitamins or laxatives) are added to the controlled substance prescriptions, maintaining relatively consistent 1:1 ratio of controlled substances to dangerous drugs and/or OTC products dispensed as prescriptions. |
| | (7) Prescriptions are authorized by the same prescriber with what appears to be different handwriting on the hardcopy prescription drug order forms. |
| | (8) Upon contact with the prescriber's office, you are unable to engage in comprehensive discussion with the actual prescriber, or he/she is unconcerned about your apprehensions regarding his/her prescribing practices or unwilling to provide additional information, such as treatment goals and/or prognosis with prescribed drug therapy. |
| | (9) You rely solely on the prescriber's representation, or on the representation of the individual answering the phone at the number on the prescription, that prescriptions are legitimate. |
| | (10) The prescriber's clinic is not registered as a pain management clinic by the Texas Medical Board, despite routinely receiving prescriptions from the prescriber foropiates, benzodiazepines, and/or muscle relaxants. |
| | (11) Drugs prescribed are inconsistent with the prescriber's area of practice. |
| | (12) The prescriber of the drugs is located a significant distance from your pharmacy. |
| | (13) The prescriber has been subject to disciplinary action by the licensing board, had his/her DEA registration removed, or been subject to criminal action. |
| | (14) The Texas PMP system indicates that persons are obtaining prescriptions for the same drugs from multiple prescribers or that persons are filling prescriptions for the same drugs at multiple pharmacies. |
| | (15) The person's address is a significant distance from your pharmacy and/or from the prescriber's office. |
| | (16) Multiple persons with the same address present prescriptions from the same prescriber. |
| | (17) Persons pay with cash or credit card more often than through insurance. |
| | (18) Persons presenting controlled substance prescriptions are doing so in such a manner that varies from seeking routine pharmacy services (e.g., willing to wait in long lines to receive drugs, persons arrive in the same vehicle with prescriptions from same prescriber, one person presents to pick up prescriptions for multiple others, persons refer to drugs by "street names" and/or comment on drug's color, persons seek early refills, persons travel from outside reasonable trade area of pharmacy). |
| | (19) Your pharmacy charges and persons are willing to pay more for controlled substances than they would at nearby pharmacies. |
| | (20) Your pharmacy routinely orders controlled substances from more than one drug supplier, or your pharmacy has been discontinued by a drug supplier related to controlled substance orders. |
| | (21) Sporadic and non-consistent dispensing volume (including zero dispensing) varies from day to day and week to week, and your pharmacy does not maintain operational hours each week on Monday through Friday. |
| | (22) Your pharmacy employs or contracts security personnel during operational hours to prevent problems. |
| | (23) Your pharmacy has been previously warned or disciplined by the Texas State Board of Pharmacy for inappropriate dispensing of controlled substances (i.e., corresponding responsibility). |

If you checked any of the above items, you should review the laws and rules regarding corresponding responsibility and non-therapeutic dispensing, especially Board rule §291.29, in the law book or on our website: www.pharmacy.texas.gov (click on Texas Pharmacy Rules and Laws). Additional educational material is available at: http://www.pharmacy.texas.gov/Nontherapeutic.asp. Failure of pharmacies and pharmacists to detect patterns of inappropriate dispensing of prescription drugs is unprofessional practice and constitutes grounds for disciplinary action.

WP pharma labs

| TITLE: | DOCUMENT NUMBER: | REVISION: | EFFECTIVE DATE: | PAGE NO: |
|---|---|---|---|---|
| Product Recall Procedure | 9.310 | 3 | 22 November 2021 | Page 1 of 15 |

| DOCUMENT APPROVAL | NAME | TITLE | SIGNATURE | DATE |
|---|---|---|---|---|
| Author/Revised by | Matt Watkins | Quality Assurance Supervisor | Signer ID: IXEQSVK3P6... | 11/18/2021 |
| Reviewer | Kim Hiddessen, PharmD | Pharmacist in Charge | Kim Hiddessen Signer ID: DACW9HY0R6... | 11/18/2021 |
| Approver | Mike Blaine | Director of Operations | Mike Blaine Signer ID: 6NAANGTVA6... | 11/18/2021 |

## 1. INTRODUCTION

It is an absolute necessity that a system exists to rapidly remove a medicinal product from use if a defect is identified that could lead to the safety, quality or efficacy of the product being compromised and hence render the product unsuitable for its intended use.

The FDA is committed to providing assistance during a recall. Recall coordinators provide information about the recall process and are available to work closely with an organization throughout the course of the recall. If assistance is needed, contact a Division Recall Coordinator within the FDA Office of Regulatory Affairs (ORA). For a comprehensive list of FDA Recall Coordinator contact information by product type and location, please visit:
https://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm

## 2. SCOPE

This procedure describes the processing of information liable to result in medicinal product corrective action (PCA) and the organization of the systems set up at WP Pharma Labs (WPPL) for medicinal product Lot recall. The systems afford the possibility of rapidly and efficiently withdrawing manufactured products from the market in case of detection or suspicion of anomalies, and also the appropriate communication to ensure products supplied and distributed by WPPL are handled accordingly (e.g. quarantined, withdrawn, etc).

## 3. REFERENCES

21 CFR 7 Subpart C – Recalls
FDA Guidance - Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C, April 2019

## 4. ASSOCIATED DOCUMENTS

9.190 Record Retention
9.280 Deviation Procedure
9.320 Pharmacovigilance Procedure

## 5. RESPONSIBILITIES

**5.1.** The QA Department is responsible for ensuring this procedure is followed and overseeing and coordinating recall activities at the site. The Site QA informs the Site Manager/PIC and the QA Manager of any manufacturing defect which could result in a medicinal product recall. If the site

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QA is not available, the Site Manager/PIC will assume the QA responsibilities for the product recall procedure.

**5.2.** The QA Manager approves all recall decisions. If the QA Manager is not available, the responsibility may be fulfilled by the Operations Manager.

**5.3.** Any person becoming aware of information liable to result in Product Corrective Action (e.g. Lot recall) is to forward the information immediately to the relevant Site QA and Management should be alerted immediately.

## 6. DEFINITIONS

**Consignee** – Anyone who received, purchased, or used the product being recalled.

**Recall** – as defined by the FDA, is a voluntary action by manufacturers to protect the public health from products that present a risk of injury or are defective. Recalls are applicable only to products that have been distributed and are not in the control of the manufacturer.

**Note**: Products enroute or products that have yet to be received by a customer are still considered to be in control by WP Pharma Labs, Inc.

## 7. PROCEDURE: NON-STERILE

**7.1.** The pharmacy shall immediately initiate a recall of any non-sterile preparation compounded by the pharmacy upon identification of a potential or confirmed harm to a patient.

**7.2. Investigate the problem**

**7.2.1.** QA department should investigate a potential problem with a product, which may include:

**7.2.1.1.** A timely investigation to determine whether a deviation in manufacturing occurred and, as applicable, whether the safety, purity, or potency of distributed products may have been affected

**7.2.1.2.** A prompt evaluation by a qualified person (Technical and Clinical evaluation by a Pharmacist and Management) and following established criteria, to ensure that potential risks are consistently assessed and investigated for products potentially affected.

**7.3. Processing of the Information Liable to Result in Product Corrective Action**

**7.3.1.** Product Corrective Action including medicinal product Lot recall of manufactured product is a decision taken in the event of:

**7.3.1.1.** Reports of adverse reactions (SOP 9.320) that could constitute a risk to public health, for which a causal relationship with the product administered, cannot be excluded and which are not listed in the summary of product characteristics as already identified effects.

**7.3.1.2.** Complaints evidencing, or giving rise to suspicion of, a quality defect.

**7.4. Practical Conditions**

**7.4.1.** The Site QA will notify the head of QA, the Site Manager/Pharmacist-in-Charge, or designee of the possibility of the need for a recall.

**7.4.2.** The Lot in question should be immediately quarantined, if a portion of the Lot is on site, and the need to examine other lots which could present the same defect is to be examined.

**7.4.3.** The Lot record and the quality control tests for the Lot will be examined in depth. Product distribution records and contact details should be immediately gathered.

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**7.5. Notification of the FDA**

**7.5.1.** If upon completion of a risk assessment there is a significant community risk, the FDA will be notified by the head of QA if a decision is made to recall a product due to detection of anomalies with distributed and unused product.

**7.5.2.** The FDA assigns the recall classification listed below based on an evaluation of the health hazard presented by the product:

**7.5.3.** Class I Recall: A situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

**7.5.4.** Class II Recall: A situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote.

**7.5.5.** Class III Recall: A situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

**7.6. Recall Actions**

**7.6.1.** When the recall decision has been taken, the QA department will execute Attachment 1 - Internal Notification of Product Recall and ensures that the following measures are immediately implemented.

**7.6.1.1.** Halt all shipments of the medicinal product Lot involved

**7.6.1.2.** Place the product, if available, in physical quarantine in an identified zone.

**7.7. Identification of Customers**

**7.7.1.** Site QA and Site Manager/Pharmacist-in-Charge obtains a list of customers to whom the product has been shipped.

**7.7.2.** The list states the quantities that have been shipped and the contact details.

**7.7.3.** Delivery companies will be contacted to allow a halt to distribution if the product is enroute.

**7.8. Customer Information and Product Recall**

**7.8.1.** It is necessary to alert all users (i.e. Physicians/Patients) of the affected product Lot or Lots requesting immediate discontinuation of use.

**7.8.2.** If deemed appropriate, a press release will also be used to notify patients.

**7.8.3.** In parallel, a Customer Notification Form (Attachment 2 - Customer Notification of Product Recall Example) is also completed and signed by the head of QA and forwarded by fax or email as rapidly as possible.

**7.9. Effectiveness Checks**

**7.9.1.** The purpose of effectiveness checks is to verify that all consignees (Physicians, Patients) have received notification about the recall and have taken appropriate action.

**7.9.2.** Consignees will be requested to complete Attachment 3 - Recall Response Form Example or may be contacted by personal visits, telephone calls, letters, or a combination thereof.

**7.9.3.** The recall strategy will specify the method(s) to be used for and the level of effectiveness checks that will be conducted, as follows:

**7.9.3.1.** Level A - 100 percent of the total number of consignees to be contacted;

**7.9.3.2.** Level B - Some percentage of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis, but is greater than 10 percent and less than 100 percent of the total number of consignees;

**7.9.3.3.** Level C - 10 percent of the total number of consignees to be contacted;

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**7.9.3.4.** Level D - 2 percent of the total number of consignees to be contacted; or
**7.9.3.5.** Level E - No effectiveness checks

**7.10. Notification of Regulatory Authorities**

**7.10.1.** The local FDA district office should be informed immediately when a decision is made to recall a product. Each site should maintain contact information for their local FDA district office.

**7.10.2.** State Boards in which the affected site is licensed will be notified within 12 hours after the recall details have been finalized with CDER.

**7.10.2.1.** If the preparation is prepared as a batch, the board is notified of the recall in writing

**7.10.2.2.** If the preparation is distributed for office use (for WPPL purposes Vet only), the Texas Dept. of State Health Services, Drugs, and Medical Devices Group, will be notified of the recall in writing

**7.11. Organization and Management of Returned Products**

**7.11.1.** In the case of product return, it is to be implemented in compliance with the appropriate legislation.

**7.11.2.** The recalled products returned are clearly identified and stored separately in a defined rejected area.

**7.11.3.** A comparative balance of the quantities distributed and recovered (or destroyed in the user departments) is compiled and a full investigation is conducted and reported.

**7.11.4.** The Product Recall Report (Attachment 4) is completed and approved by the Site QA or designee.

**7.12. Third-Party Recalls**

**7.12.1.** In the event that a Vendor issues a recall on a product (i.e. drug product or device) that has been used in the preparation of a WP Pharma Labs product, a reconciliation (Attachment 5 - Third Party Product Recall Form) must be completed and customers who have received affected product will be notified (Attachment 6 - Customer Notification of Third-Party Product Recall Example).

**7.13. Records**

**7.13.1.** The records and archiving of the documents relating to medicinal product Lot recall are placed under the authority of the site QA. Refer to SOP 9.190 Record Retention.

**7.13.2.** A paper and hardcopy file are maintained which contains all details relevant to the inquiry including follow up investigations and the recommended corrective and/or preventative actions.

**8. PROCEDURE – STERILE**

**8.1.** The pharmacy shall immediately initiate a recall of any sterile preparation compounded by the pharmacy upon identification of a potential or confirmed harm to a patient.

**8.2. Investigate the problem**

**8.2.1.** QA department should investigate a potential problem with a product, which may include:

**8.2.1.1.** A timely investigation to determine whether a deviation in manufacturing occurred and, as applicable, whether the safety, purity, or potency of distributed products may have been affected

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**8.2.1.2.** A prompt evaluation by a qualified person (Technical and Clinical evaluation by a Pharmacist and Management) and following established criteria, to ensure that potential risks are consistently assessed and investigated for products potentially affected.

**8.3. Processing of the Information Liable to Result in Product Corrective Action**

**8.3.1.** Product Corrective Action including medicinal product Lot recall of manufactured product is a decision taken in the event of:

**8.3.1.1.** Reports of adverse reactions (SOP 9.320) that could constitute a risk to public health, for which a causal relationship with the product administered, cannot be excluded and which are not listed in the summary of product characteristics as already identified effects.

**8.3.1.2.** Complaints evidencing, or giving rise to suspicion of, a quality defect.

**8.4. Practical Conditions**

**8.4.1.** The Site QA will notify the head of QA, the Site Manager/Pharmacist-in-Charge, or designee of the possibility of the need for a recall.

**8.4.2.** The Lot in question should be immediately quarantined, if a portion of the Lot is on site, and the need to examine other lots which could present the same defect is to be examined.

**8.4.3.** The Lot record and the quality control tests for the Lot will be examined in depth. Product distribution records and contact details should be immediately gathered.

**8.5. Notification of the FDA**

**8.5.1.** If upon completion of a risk assessment there is a significant community risk, the FDA will be notified by the head of QA if a decision is made to recall a product due to detection of anomalies with distributed and unused product.

**8.5.2.** The FDA assigns the recall classification listed below based on an evaluation of the health hazard presented by the product:

**8.5.3.** Class I Recall: A situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

**8.5.4.** Class II Recall: A situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote.

**8.5.5.** Class III Recall: A situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

**8.6. Recall Actions**

**8.6.1.** When the recall decision has been taken, the QA department will execute Attachment 1 - Internal Notification of Product Recall and ensures that the following measures are immediately implemented.

**8.6.1.1.** Halt all shipments of the medicinal product Lot involved

**8.6.1.2.** Place the product, if available, in physical quarantine in an identified zone.

**8.7. Identification of Customers**

**8.7.1.** Site QA and Site Manager/Pharmacist-in-Charge obtains a list of customers to whom the product has been shipped.

**8.7.2.** The list states the quantities that have been shipped and the contact details.

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**8.7.3.** Delivery companies will be contacted to allow a halt to distribution if the product is enroute.

**8.8. Customer Information and Product Recall**

**8.8.1.** It is necessary to alert all users (i.e. Physicians/Patients) of the affected product Lot or Lots requesting immediate discontinuation of use.

**8.8.2.** If deemed appropriate, a press release will also be used to notify patients.

**8.8.3.** In parallel, a Customer Notification Form (Attachment 2 - Customer Notification of Product Recall Example) is also completed and signed by the head of QA and forwarded by fax or email as rapidly as possible.

**8.9. Effectiveness Checks**

**8.9.1.** The purpose of effectiveness checks is to verify that all consignees (Physicians, Patients) have received notification about the recall and have taken appropriate action.

**8.9.2.** Consignees will be requested to complete Attachment 3 - Recall Response Form Example or may be contacted by personal visits, telephone calls, letters, or a combination thereof.

**8.9.3.** The recall strategy will specify the method(s) to be used for and the level of effectiveness checks that will be conducted, as follows:

**8.9.3.1.** Level A - 100 percent of the total number of consignees to be contacted;

**8.9.3.2.** Level B - Some percentage of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis, but is greater than 10 percent and less than 100 percent of the total number of consignees;

**8.9.3.3.** Level C - 10 percent of the total number of consignees to be contacted;

**8.9.3.4.** Level D - 2 percent of the total number of consignees to be contacted; or

**8.9.3.5.** Level E - No effectiveness checks

**8.10. Notification of Regulatory Authorities**

**8.10.1.** The local FDA district office should be informed immediately when a decision is made to recall a product. Each site should maintain contact information for their local FDA district office.

**8.10.2.** State Boards in which the affected site is licensed will be notified within 12 hours after the recall details have been finalized with CDER.

**8.10.2.1.** WPPL shall notify the board immediately of any adverse effects reported to the pharmacy or that are known by the pharmacy to be potentially attributable to a sterile preparation compounded by the pharmacy

**8.10.2.2.** If the preparation is prepared as a batch, the board is notified of the recall in writing

**8.10.2.3.** If the preparation is distributed for office use (not applicable), the Texas Dept. of State Health Services, Drugs, and Medical Devices Group, will be notified of the recall in writing

**8.11. Organization and Management of Returned Products**

**8.11.1.** In the case of product return, it is to be implemented in compliance with the appropriate legislation.

**8.11.2.** The recalled products returned are clearly identified and stored separately in a defined rejected area.

**8.11.3.** A comparative balance of the quantities distributed and recovered (or destroyed in the user departments) is compiled and a full investigation is conducted and reported.

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**8.11.4.** The Product Recall Report (Attachment 4) is completed and approved by the Site QA or designee.

**8.12. Third-Party Recalls**

**8.12.1.** In the event that a Vendor issues a recall on a product (i.e. drug product or device) that has been used in the preparation of a WP Pharma Labs product, a reconciliation (Attachment 5 - Third Party Product Recall Form) must be completed and customers who have received affected product will be notified (Attachment 6 - Customer Notification of Third-Party Product Recall Example).

**8.13. Records**

**8.13.1.** The records and archiving of the documents relating to medicinal product Lot recall are placed under the authority of the site QA. Refer to SOP 9.190 Record Retention.

**8.13.2.** A paper and hardcopy file are maintained which contains all details relevant to the inquiry including follow up investigations and the recommended corrective and/or preventative actions.

## 9. ATTACHMENTS

**9.1.** Attachments are suggested templates and the necessary information will be included as dictated by the classification and size of the recall.

Attachment 1 – Internal Notification of Product Recall
Attachment 2 – Customer Notification of Product Recall Example
Attachment 3 – Recall Response Form Example
Attachment 4 – Product Recall Report
Attachment 5 – Third Party Product Recall Form
Attachment 6 – Customer Notification of Third-Party Product Recall Example

## 10. REVISION HISTORY

| Revision | Details of changes | Change Control # | Effective Date |
|---|---|---|---|
| 1 | New document | N/A | 28 August 2019 |
| 2 | Updated Attachments Internal Notification and Customer Notification; Added Attachment 3 - Recall Response Form Example, Attachment 5 - Third Party Product Recall, and Attachment 6 - Customer Notification of Third-Party Product Recall Example; minor formatting adjustments | CC-DL-2020-011 | 17 February 2020 |
| 3 | Amended Section 7 to Non-Sterile Recall Procedure<br>Added section 7.1 Immediate initiation of recall if suspected or reported adverse reaction | CC-DL-2021-001 | 22 November 2021 |

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| | | | |
|---|---|---|---|
| | Added section 7.10.2.1 and 7.10.2.2 to explain the notification procedure of state boards<br>Added Section 8 – Sterile Recall Procedure<br>Added sections 8.10.2.1, 8.10.2.2, and 8.10.2.3 to explain the notification procedure of state boards | | |

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**Attachment 1 – Internal Notification of Product Recall**

## Internal Notification of Product Recall

| | | | |
|---|---|---|---|
| **This document is intended for internal communication only and is not to be shared with parties outside of WPPL. This document is to be distributed to the following WPPL personnel.** | | | |
| **Site Manager or designee:** | | | |
| **Pharmacist-in-Charge:** | | | |
| **GMP Consultant:** | | | |
| **Quality Assurance Manager:** | | | |
| **Upon receipt of this document immediately discontinue distributing the product listed below, quarantine the quantities available in an identified zone.** | | | |
| **Affected Product Name:** | | | |
| **Affected Product Lot #:** | | | |
| **QA Signature:** | | **Date:** | |
| **Receipt of this document is acknowledged by the following WPPL personnel. Signatures must be made with wet, indelible ink or via HelloSign.** | | | |
| **Site Manager or designee:** | | **Date:** | |
| **Pharmacist-in-Charge:** | | **Date:** | |
| **GMP Consultant:** | | **Date:** | |
| **Quality Assurance Manager:** | | **Date:** | |
| **Reconciliation of the affected product.** | | | |
| **Total number of doses or prescriptions produced:** | | | |
| **Number of doses or prescriptions shipped:** | | | |
| **Number of doses or prescriptions quarantined:** | | | |

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## Attachment 2 – Customer Notification of Product Recall Example

## Customer Notification of Product Recall Example

Dear WP Pharma Labs Customer,

WP Pharma Labs Inc. ("WPPL") is initiating a voluntary recall of <product name>. The affected lot information is listed below. This product is being voluntarily recalled due to <insert reason>.

| | | | |
|---|---|---|---|
| **Product Name:** | | | |
| **Lot #:** | | **BUD / Expiration Date:** | |

**To reduce any risk, we ask for your cooperation in taking the following action:**

Discontinue use of <product name> <Lot #> and quarantine any unused product.
Complete the enclosed Recall Response Form and return to WPPL immediately upon receipt.

Yours sincerely,

<QA Signature>
<Title>

---

Customers with questions regarding this recall can contact WP Pharma Labs at 800-441-0048 Monday through Friday between 8:00 am and 4:00 pm EST or email at khiddessen@wppharmalabs.com.

Adverse reactions or quality problems experienced may be reported to FDA in the following ways:

Online: Complete and submit the form at www.fda.gov/medwatch/report.htm.
U.S. Mail or Fax: Download form at www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form. Complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

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## Attachment 3 – Recall Response Form Example
## Recall Response Form Example

**Please immediately return the completed response form to WPPL in the enclosed envelope or scan/email to khiddessen@wppharmalabs.com. This response is required for the affected product listed below.**

| | | | |
|---|---|---|---|
| **Product Name** | <to be entered by WPPL> | | |
| **Lot #** | <to be entered by WPPL> | **BUD / Expiration Date** | <to be entered by WPPL> |

| | | | |
|---|---|---|---|
| **Name** | | | |
| **Address** | | | |
| **City, State, ZIP** | | | |
| **Telephone Number** | | | |
| **Email Address (optional)** | | | |
| **Product on Hand** | Yes No | **Quantity on Hand** | #_____ or N/A |
| **Disposition of Product** | **Returned to WPPL** **Destroyed**<br>*Contact WPPL if you are unsure of the correct method.* | | |
| **Have you experienced any Adverse Events associated with this Product?** | Yes No | **If Yes, please provide detail:** | |
| **I have read and understood the recall instructions provided to me in the Recall Notification Letter** | | Yes No | |
| **Signature:** | | **Date:** | |

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**Attachment 4 – Product Recall Report** **Page 1 of 2**

## Product Recall Report

| Site: | Lot number(s): | Date initiated: |
|---|---|---|
| **Reason and justification for recall** | | |
| **Reason for Recall:**<br><br>**Investigation (including review of Lot record and analytical results):**<br><br>**Test/retest results summary (attach copies of alt chromatograms, printouts):** | | |
| **FDA Notification Date and Details:** | | |
| **QA Signature:** | **Date:** | |
| **GMP Consultant** | **Date:** | |

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**Attachment 4 – Product Recall Report** **Page 2 of 2**

| Recalled Doses | | | |
|---|---|---|---|
| **Customer/Patient** | **Rx / Prescription #** | **Courier or Customer Notified** | **Date / Time of Notification** |
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| **Signature:** | | | **Date:** |

| Returned Doses | | | |
|---|---|---|---|
| **Customer/Patient** | **Rx / Prescription #** | **Courier or Customer Notified** | **Date / Time of Notification** |
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| **Signature:** | | | **Date:** |

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## Attachment 5 – Third Party Product Recall Form

## Third Party Product Recall Reconciliation Form

| | |
|---|---|
| **Site:** | **Date:** |
| **Third Party Issuing Recall:** | **Date of Notification:** |
| **Product Name(s):** | **Product Lot(s):** |
| **Class:**<br>☐ Class 1 Recall<br>☐ Class 2 Recall<br>☐ Class 3 Recall | **Reason for Recall:** |
| **Recalled Lots Currently In Stock:**<br>☐ N/A _____ units | **Recalled Lots Quarantined:**<br>☐ N/A _____ units |

**Recalled Lots Dispensed:**
☐ N/A

Order #: _____ Lot #: _____ Dispensed Date: _____
Recall Notification Initiated: ☐ Yes ☐ No Date of Notification: _____

Order #: _____ Lot #: _____ Dispensed Date: _____
Recall Notification Initiated: ☐ Yes ☐ No Date of Notification: _____

Order #: _____ Lot #: _____ Dispensed Date: _____
Recall Notification Initiated: ☐ Yes ☐ No Date of Notification: _____

Order #: _____ Lot #: _____ Dispensed Date: _____
Recall Notification Initiated: ☐ Yes ☐ No Date of Notification: _____

Order #: _____ Lot #: _____ Dispensed Date: _____
Recall Notification Initiated: ☐ Yes ☐ No Date of Notification: _____

Order #: _____ Lot #: _____ Dispensed Date: _____
Recall Notification Initiated: ☐ Yes ☐ No Date of Notification: _____

Order #: _____ Lot #: _____ Dispensed Date: _____
Recall Notification Initiated: ☐ Yes ☐ No Date of Notification: _____

| | | | |
|---|---|---|---|
| **Initiator Signature** | | **Date** | |
| **QA Signature** | | **Date** | |

NOTICE
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WP pharma labs

| TITLE: | DOCUMENT NUMBER: | REVISION: | EFFECTIVE DATE: | PAGE NO: |
|---|---|---|---|---|
| Product Recall Procedure | 9.310 | 3 | 22 November 2021 | Page 15 of 15 |

## Attachment 6 – Customer Notification of Third-Party Product Recall Example

### Customer Notification of Third-Party Product Recall Example

Dear WP Pharma Labs Customer,

<Third-Party Vendor Name> is initiating a voluntary recall of <Product Name>.This product is being voluntarily recalled due to <insert reason>.

<Insert verbiage from third-party vendor recall notice>

<Third-Party Vendor Name> **provided the affected lot information below:**

| Product Description | NDC Number | Lot Number | Expiration Date |
|---|---|---|---|
| <Product Name> | <NDC #> | <Lot #> | <Expiration Date> |

**To reduce any risk, we ask for your cooperation in taking the following action:**

- Discontinue use of <Third-Party Vendor Name> <Product Name>, as well as any product mixture in which it was used.
- Quarantine any unused product and Contact WPPL at 800-441-0048 Monday through Friday, between 8:00 am and 4:00 pm CST or email at khiddessen@wppharmalabs.com to discuss the return of any unused product.
- Customers with questions regarding this recall can contact WPPL at 800-441-0048 Monday through Friday between 8:00 am and 4:00 pm CST or email at khiddessen@wppharmalabs.com
- Providers who have dispensed this product to a patient(s) for use outside of the provider's office should contact the patient(s) to whom the product was dispensed and advise the patient(s) of this recall.
- Adverse reactions or quality problems experienced with the use of <Third-Party Vendor Name> <Product Name> may be reported to FDA in the following ways:

  Online: Complete and submit the form at www.fda.gov/medwatch/report.htm.

  U.S. Mail or fax: Download form at www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form. Complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

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# Signature Certificate

**Envelope Ref: 7a70fc124afb6aba15de6774ba9219be63ca7246**

| Author | Creation Date | Completion Date |
|---|---|---|
| Matt Watkins | 18 Nov 2021, 11:25:42, PST | 18 Nov 2021, 14:15:18, PST |

## Document Details:



| | |
|---|---|
| Name: | 9.310 Product Recall Procedure - Rev. 3 |
| Type: | |
| Document Ref: | 7bba6b7a0ffc11fdc8d18a3550ff27392bc113d15add350d092c586f605eb4dd |
| Document Total Pages: | 15 |

## Document Signed By:

| | |
|---|---|
| Name: | Matt Watkins |
| Email: | mwatkins@wppharmalabs.com |
| IP: | 98.156.26.122 |
| Location: | AUSTIN, TX (US) |
| Date: | 18 Nov 2021, 11:31:55, PST |
| Consent: | eSignature Consent Accepted |
| Security Level: | Email |

Signer ID: IXEQSVK3P6...

| | |
|---|---|
| Name: | Mike Blaine |
| Email: | mblaine@wppharmalabs.com |
| IP: | 108.252.120.168 |
| Location: | SEASIDE, CA (US) |
| Date: | 18 Nov 2021, 11:33:25, PST |
| Consent: | eSignature Consent Accepted |
| Security Level: | Email |

Signer ID: 6NAANGTVA6...

| | |
|---|---|
| Name: | Kim Hiddessen |
| Email: | khiddessen@wppharmalabs.com |
| IP: | 2600:387:1:811::59 |
| Location: | DALLAS, TX (US) |
| Date: | 18 Nov 2021, 14:15:17, PST |
| Consent: | eSignature Consent Accepted |
| Security Level: | Email |

Signer ID: DACW9HY0R6...

## Document History:

| | |
|---|---|
| Envelope Created | Matt Watkins created this envelope on 18 Nov 2021, 11:25:42, PST |
| Invitation Sent | Invitation sent to Matt Watkins on 18 Nov 2021, 11:31:36, PST |
| Invitation Sent | Invitation sent to Kim Hiddessen on 18 Nov 2021, 11:31:36, PST |
| Invitation Sent | Invitation sent to Mike Blaine on 18 Nov 2021, 11:31:36, PST |

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| | |
|---|---|
| Invitation Accepted | Invitation accepted by Matt Watkins on 18 Nov 2021, 11:31:37, PST |
| Signed By Matt Watkins | Matt Watkins signed this envelope on 18 Nov 2021, 11:31:55, PST |
| Invitation Accepted | Invitation accepted by Mike Blaine on 18 Nov 2021, 11:33:10, PST |
| Signed By Mike Blaine | Mike Blaine signed this envelope on 18 Nov 2021, 11:33:25, PST |
| Invitation Accepted | Invitation accepted by Kim Hiddessen on 18 Nov 2021, 14:14:39, PST |
| Signed By Kim Hiddessen | Kim Hiddessen signed this envelope on 18 Nov 2021, 14:15:17, PST |
| Executed | Document(s) successfully executed on 18 Nov 2021, 14:15:18, PST |
| Signed Document(s) | Link Emailed to mwatkins@wppharmalabs.com |
| Signed Document(s) | Link Emailed to khiddessen@wppharmalabs.com |
| Signed Document(s) | Link Emailed to mblaine@wppharmalabs.com |

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| TITLE: | DOCUMENT NUMBER | REVISION | EFFECTIVE DATE | PAGE NO8: |
|---|---|---|---|---|
| Change Control Form | FRM-9.380.01 | 1 | 28 August 2019 | 1 of 3 |

# Change Control Form

| Request Initiation | | |
|---|---|---|
| **Initiator Name** | Matt Watkins | ☐ **Process**<br>☐ **Vendor**<br>☐ **Analytical Technique**<br>☐ **Equipment**<br>☒ **SOP**<br>☐ **Documentation** |
| **Current Situation** | 1. SOP 9.310 Product Recall Procedure (Rev 2) missing required procedure per Texas State Board of Pharmacy Rule 291.131G (Non-Sterile) and 291.133G (Sterile) stating that each compound type should have its own procedure. | |
| **Change(s) to be Implemented** | 1. Add sections that delineate a sterile recall and a non-sterile recall. | |
| **Expected Outcome** | 1. SOP will be updated to ensure proper verbiage in accordance with (g) Recall Procedures in TSBP Rules (pg. 265 sterile and pg. 231, non-sterile) on version 9/29/2021. | |
| **Site(s)/ Department(s) Affected** | Sterile Lab Dept., Non-sterile Lab Dept., and Quality Dept., | |

| TITLE: | DOCUMENT NUMBER | REVISION | EFFECTIVE DATE | PAGE NO8: |
|---|---|---|---|---|
| Change Control Form | FRM-9.380.01 | 1 | 28 August 2019 | 2 of 3 |

| Impact Analysis |
|---|
| Additional equipment or modification of existing equipment: If yes, comment below ☒ NA |
| New materials, or new specifications for existing materials: If yes, comment below ☒ NA |
| Qualification of vendors: If yes, comment below ☒ NA |
| Development of new procedures or Review of existing procedures: If yes, comment below ☒ NA<br>☐ No changes need to be implemented<br>☐ SOP Change Control is attached to update the procedure:<br>☐ SOP should be obsoleted, Change Control Log Number _____ |
| Requalification of equipment or revalidation of processes: If yes, comment below ☒ NA |
| Revision/creation of documents affected by the change: If yes, comment below ☐ NA<br>Internal Notification of Product Recall Form<br>Customer Notification of Product Recall Form<br>Recall Response Form<br>Product Recall Report Form<br>Third Party Product Recall Form<br>Customer Notification of Third-Party Recall Form |
| Training requirements: If yes, comment below ☐ NA<br>Staff will be retrained in proper procedures in 9.310 Rev 3. |
| Other: ☒ NA |

| | | | |
|---|---|---|---|
| **Initiator Signature** | M Watkins<br>Signer ID: IXEQSVK3P6... | **Date** | 11/18/2021 |
| | **QA Approval** | | |
| **Change Control Number** | **CC-DL-2021-001** | | |
| **Assigned by** | **Matt Watkins** | **Date** | **18 Nov 2021** |

| TITLE: | DOCUMENT NUMBER | REVISION | EFFECTIVE DATE | PAGE NO8: |
|---|---|---|---|---|
| Change Control Form | FRM-9.380.01 | 1 | 28 August 2019 | 3 of 3 |

| Department | Approval Signature | Date |
|---|---|---|
| **Quality Assurance**<br>☐ **Approved**<br>☐ **Rejected** | Signer ID: IXEQSVK3P6... | 11/18/2021 |
| **Pharmacy Operations**<br>☐ **Approved**<br>☐ **Rejected** | Mike Blaine<br>Signer ID: 6NAANGTVA6... | 11/18/2021 |
| **Pharmacist**<br>☐ **Approved**<br>☐ **Rejected** | Kim Hiddessen<br>Signer ID: DACW9HY0R6... | 11/18/2021 |
| **Other (If Applicable):**<br>☐ **Approved**<br>☐ **Rejected** | | |

**Reason for Rejection:**

Doc ID: f30733687a9af0c3cc4d1176a27bc1a8ea0f5973

# Signature Certificate

**Envelope Ref: e655918ff1654299405fce90d90b84e61afed3f2**

| Author: | Matt Watkins | Creation Date: | 18 Nov 2021, 10:43:28, PST | Completion Date: | 18 Nov 2021, 14:19:39, PST |
|---|---|---|---|---|---|

## Document Details:



| | |
|---|---|
| Name: | 9.380.01 - Change Control Form - CC-DL-2021-001 |
| Type: | |
| Document Ref: | 9edf08e327cf47cd38b4c50c04c680de9bf31224416b1a106e9a10466eadc626 |
| Document Total Pages: | 3 |

## Document Signed By:

| | |
|---|---|
| Name: | Matt Watkins |
| Email: | mwatkins@wppharmalabs.com |
| IP: | 98.156.26.122 |
| Location: | AUSTIN, TX (US) |
| Date: | 18 Nov 2021, 10:50:53, PST |
| Consent: | eSignature Consent Accepted |

Signer ID: IXEQSVK3P6...

| | |
|---|---|
| Name: | Kim Hiddessen |
| Email: | khiddessen@wppharmalabs.com |
| IP: | 98.156.26.122 |
| Location: | AUSTIN, TX (US) |
| Date: | 18 Nov 2021, 14:19:38, PST |
| Consent: | eSignature Consent Accepted |
| Security Level: | Email, Two-factor Authentication via Email |

Signer ID: DACW9HY0R6...

| | |
|---|---|
| Name: | Mike Blaine |
| Email: | mblaine@wppharmalabs.com |
| IP: | 108.252.120.168 |
| Location: | SEASIDE, CA (US) |
| Date: | 18 Nov 2021, 10:51:09, PST |
| Consent: | eSignature Consent Accepted |
| Security Level: | Email, Two-factor Authentication via Email |

Signer ID: 6NAANGTVA6...

## Document History:

| | |
|---|---|
| Envelope Created: | Matt Watkins created this envelope on 18 Nov 2021, 10:43:28, PST |
| Invitation Sent: | Invitation sent to Matt Watkins on 18 Nov 2021, 10:50:12, PST |
| Invitation Sent: | Invitation sent to Mike Blaine on 18 Nov 2021, 10:50:12, PST |
| Invitation Sent: | Invitation sent to Kim Hiddessen on 18 Nov 2021, 10:50:12, PST |
| Invitation Accepted: | Invitation accepted by Matt Watkins on 18 Nov 2021, 10:50:12, PST |

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| | |
|---|---|
| Authentication Code Emailed | Authentication Code Emailed to Mike Blaine on 18 Nov 2021, 10:50:32, PST |
| Signed By Matt Watkins | Matt Watkins signed this envelope on 18 Nov 2021, 10:50:53, PST |
| Authentication Code Validated | Authentication Code Validated by Mike Blaine on 18 Nov 2021, 10:50:54, PST |
| Invitation Accepted | Invitation accepted by Mike Blaine on 18 Nov 2021, 10:50:54, PST |
| Signed By Mike Blaine | Mike Blaine signed this envelope on 18 Nov 2021, 10:51:09, PST |
| Authentication Code Emailed | Authentication Code Emailed to Kim Hiddessen on 18 Nov 2021, 14:15:53, PST |
| Authentication Code Validated | Authentication Code Validated by Kim Hiddessen on 18 Nov 2021, 14:19:17, PST |
| Invitation Accepted | Invitation accepted by Kim Hiddessen on 18 Nov 2021, 14:19:18, PST |
| Signed By Kim Hiddessen | Kim Hiddessen signed this envelope on 18 Nov 2021, 14:19:38, PST |
| Executed | Document(s) successfully executed on 18 Nov 2021, 14:19:39, PST |
| Signed Document(s) | Link Emailed to mwatkins@wppharmalabs.com |
| Signed Document(s) | Link Emailed to mblaine@wppharmalabs.com |
| Signed Document(s) | Link Emailed to khiddessen@wppharmalabs.com |

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# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (04/22/2021)

### Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: WP Pharma Labs, Inc.

Physical Address: 4001 McEwen Ste. 110

City: Dallas State: TX Zip: 75244

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 469-722-4500 Website: WPPharmalabs.com

Licensing Company Email: regulatoryaffairs@wppharmalabs.com

### Section 2: Personal Information

First: Faiez Middle: H Last: Usman

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Colonnade Drive

City: Irving State: TX Zip: 75039

Telephone: [redacted] Email: fusman@wppharmalabs.com

Are you a citizen of the United States? ■ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/Reserves ☐ Navy/Reserves ☐ Airforce/Reserves ☐ Marine Corps/Reserves ☐ Coast Guard/Reserves ☐ National Guard

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✔ |

Applicant's initials: FR

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Address | City | State | Zip |
| Diploma/Degree obtained, if any | | | |
| School Name | | From - To (MM/YY – MM/YY) | |
| Address | City | State | Zip |
| Diploma/Degree obtained, if any | | | |
| School Name | | From - To (MM/YY – MM/YY) | |
| Address | City | State | Zip |
| Diploma/Degree obtained, if any | | | |
| School Name | | From - To (MM/YY – MM/YY) | |
| Address | City | State | Zip |
| Diploma/Degree obtained, if any | | | |
| School Name | | From - To (MM/YY – MM/YY | |
| Address | City | State | Zip |
| Diploma/Degree obtained, if any | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| | ATTACHED | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

Applicant's initials _____

Faiez Usman List of Addresses over the last 10 years

1. **09/2011 – 09/2012** [redacted] Goodman Ave, apt 3312, Addison, TX 75001
2. **09/2012 – 12/2014** [redacted] E Royal Ln, Apt 2111, Irving, TX 75039
3. **12/2014 - 03/2021** [redacted] Longmeadow Hill Dr., Irving, TX 75063
4. **08/2017 - 12/2017** [redacted] E Sonterra Blvd, Apt 5302, San Antonio, TX 78258
5. **03/21 - 06/21** [redacted] E Cityline Dr., Apt [redacted], Richardson, TX 75082
6. **06/21 - Present** [redacted] Colonnade Dr, Irving TX 75039

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| | | | | |
|---|---|---|---|---|
| Business Name<br>See attached | | | From - To (MM/YY – MM/YY) | |
| Business Address | City | | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| | | | | |
|---|---|---|---|---|
| Business Name | | | From - To (MM/YY – MM/YY) | |
| Business Address | City | | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| | | | | |
|---|---|---|---|---|
| Business Name | | | From - To (MM/YY – MM/YY) | |
| Business Address | City | | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| | | | | |
|---|---|---|---|---|
| Business Name | | | From - To (MM/YY – MM/YY) | |
| Business Address | City | | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| | | | | |
|---|---|---|---|---|
| Business Name | | | From - To (MM/YY – MM/YY) | |
| Business Address | City | | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Continue on next page if additional space is needed.

# Faiez Usman

6869 Colonnade Dr. ♦ Irving, Texas 75039
Phone (630) 709-5480 ♦ faiez.usman@gmail.com

## EDUCATION

**Doctor of Pharmacy (Pharm.D.)**
Midwestern University, Chicago College of Pharmacy, Downers Grove, IL, March 2010
**Pre-Pharmacy**
Benedictine University, Lisle, IL, 2006

## PROFESSIONAL EXPERIENCE

**WP Pharma Labs** **04/2022 - Present**

**President**

**Strukmyer Pharma** **07/2018 – 04/2022**

**Director of Pharma - Pharmacist-in-Charge**

**ASP Cares Pharmacy** **08/2017 - 7/2018**

**Director of 503B Operations**

**RxProStaff** **12/2011 - 08/2017**

**Corporate Pharmacy Manager**

**ATRIUM MEDICAL CENTER, Corinth, TX** **12/2010 – 11/2011**

**Staff Pharmacist**

**INTEGRA REHAB HOSPITAL PLANO, Plano, TX** **06/2010 – 12/2010**

**Staff Pharmacist**

**RXPROSTAFF INC, Colleyville, TX** **06/2010 – 08/2017**

**Agency Pharmacist**
USMD HOSPITAL, Arlington, TX
INTEGRITY REHAB, Denton, TX
PHARMACY SOLUTIONS, Arlington, Texas

## ADDITIONAL PROFESSIONAL EXPERIENCE

OSCO PHARMACY, Naperville, IL **10/2004 – 06/2005**
**Pharmacy Technician**

## PHARMACY LICENSURE

Texas State Board of Pharmacy Registered Pharmacist License, July 2010 - Present

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

Applicant's initials _____

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✔ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

I, Faiez Usman, **certify that as the designated representative for** WP Pharma Labs, Inc.,

**that I am qualified as follows and will comply with the following:**

1. I am at least 21 years of age;
3. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. I will serve in this representative capacity for only one pharmacy or wholesaler at a time

Faiez Usman

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/6/23

Date

Applicant's initials

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Faiez Usman

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/6/23

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Texas, ss. County of Dallas

I, Faiez Usman, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

2/6/23

**Date**

Subscribed and Sworn to before me this 6TH day of February, 2023

Martha Rozell

**Notary Public Signature**

MARTHA ROZELL
My Notary ID # 6450477
Expires April 16, 2024

**(Seal)**

Applicant's initials

# 8E

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/02/2022)

Y

| Facility Location | Application Type (check all applicable) | Pharmacy Type (check all applicable) | Services the Pharmacy will Provide (check all applicable) |
|---|---|---|---|
| ☐ Nevada | ■ New Pharmacy | ■ Retail/Community | ■ Retail/Community |
| ■ Out-of-State | ☐ Ownership Change* | ☐ Hospital (# beds _____) | ■ Non-sterile Compounding |
| | ☐ Location Change * | ☐ Internet | ■ Sterile Compounding |
| | ☐ Name Change* | ☐ Nuclear | ■ Mail-Order Service |
| | | ☐ Other: | ☐ Off-site Cognitive Services |
| | * If making a change, provide license #: | | ☐ Long Term Care |
| | | | ☐ Hospital |
| | PH_____ | | ☐ Other: |

| Days of Operation | | Ownership Type (check applicable box) |
|---|---|---|
| ■ Monday | ■ Friday | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12) |
| ■ Tuesday | ■ Saturday | ■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12) |
| ■ Wednesday | ☐ Sunday | ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12) |
| ■ Thursday | ☐ Holidays | ■ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12) |

### Section 1: General Information

Pharmacy Name: Pope Shenouda LLC, DBA 1st Choice Pharmacy

Physical Address: 2228 US HWY 19 N

City: Holiday State: FL Zip: 34691

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 727-934-1300 Toll Free # (NAC 639.708, NRS 639.23286): 844-565-5155

Fax: 727-934-1313 Contact Email: firstchoicepharmacy@yahoo.com

Website: www.1stchoicepharmacy.net

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Joseph Bishay ✓

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23157 ✓

**Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)**

| | |
|---|---|
| Name: Joseph Bishay | NV Pharmacist Registration #: 23157 |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |

| Section 3: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✔ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction? | ✔ | |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry? | | ✔ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✔ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✔ |

**If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.**

**Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)**

| | | |
|---|---|---|
| Name: N/A | Credentials: N/A | %: N/A |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

**Section 5: Publicly Traded Corporation**

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 6: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: Florida

Parent Company (if any): _____

Corporation/Organization Name: Pope Shenouda LLC

Mailing Address: 2228 US Hwy 19 N

City: Holiday State: FL Zip: 34691

Telephone: 727-934-1300 Email: _____

Contact Person Name: George Hanna

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

**Section 7: Partnership**

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 8: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

**Section 9: Statement of Responsibility – MUST BE COMPLETED by an Authorized Person (NAC 639.945)**

## Statement of Responsibility

1. I am the Owner (title) for Pope Shenouda LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

George Hanna

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

09/21/2022

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

George Hanna

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

09/21/2022

Date

| Board Use Only | Date Received: 12-14-22 | Amount: 500.00 CK-4552 |
|---|---|---|

ec ? also

# Arkansas State Board of Pharmacy

322 South Main Street, Suite 600 Little Rock, AR 72201
P: 501.682.0190 F: 501.682.0195
asbp@arkansas.gov • www.pharmacyboard.arkansas.gov
John Clay Kirtley, Pharm.D., Executive Director


March 18, 2022

George Hanna
1st Choice Pharmacy
2228 US Hwy. 19
Holiday, FL 34691

VIA CERTIFIED MAIL: 70200640000149160844
VIA STANDARD MAIL

RE: Denial Letter of Application for Out-of- State Pharmacy License

Dear Mr. Hanna:

The Arkansas State Board of Pharmacy has administratively denied your application for an out-of-state pharmacy Permit. The denial is based on your Florida and VPP inspections.

You may appeal this administrative denial of your application to a full board hearing under the Arkansas Administrative Procedures Act, Ark. Code Ann. § 25-15-201, *et seq.*, by notifying this office in writing within thirty (30) days of receipt of this letter.

If you have any questions, please contact the Board office at 501-682-0190.

Sincerely,

Luke Daniel
General Counsel

# Nevada State Board of Pharmacy

985 Damonte Ranch Parkway, Suite 206 • Reno, NV 89521
(775) 850-1440 • FAX (775) 850-1444
E-mail: bkandt@pharmacy.nv.gov • Web Page: bop.nv.gov


January 18, 2021

**VIA U.S. CERTIFIED MAIL**

George Hanna
Pope Shenouda LLC
d/b/a 1st Choice Pharmacy
2228 US Hwy 19 North
Holiday, FL 34691

***Re: Notice of Denial - Application for Out-of-State Compounding Pharmacy License***

Dear Mr. Hanna:

This constitutes notice pursuant to NRS 639.138 that the Nevada State Board of Pharmacy (Board) on January 13, 2021, denied your application pursuant to NRS 639.2328 for an out-of-state compounding pharmacy license. The Board denied your application pursuant to NRS 639.23282 due to your failure to present evidence satisfactory to the Board as to competency, qualifications and credentials. That denial was based on information and testimony presented during the hearing on the application; a copy of the audio recording of the hearing is available to you upon request.

Pursuant to NRS 639.139 you have the right to petition the Board for reconsideration of your application within thirty (30) days of receipt of this notice, and the right to submit evidence to controvert the basis for denial. To petition for reconsideration please submit the petition and all evidence in support thereof to the Board at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521.

If you have any questions, please do not hesitate to contact me at 775-850-1440 or bkandt@pharmacy.nv.gov.

Best regards,

Brett Kandt
General Counsel
Nevada State Board of Pharmacy

Enclosures

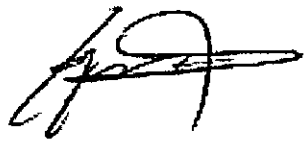
# 1st Choice Pharmacy

From:
George Hanna, RPh
1st Choice Pharmacy
2228 US Hwy 19 N
Holiday, FL 34691

To Whom It May Concern:

The application for licensure as a non-resident pharmacy with the state of Nevada was denied. Per the Nevada board of pharmacy, approval would be considered given additional training and competencies of the sterile compounding staff. 1st Choice Pharmacy is currently providing additional sterile compounding trainings to the compounding staff and gathering materials to submit to the Nevada Board to prove competency. Compounding staff is also completing several continuing education courses on the subject of sterile compounds. 1st Choice Pharmacy plans to re-apply to Nevada as a non-resident pharmacy in the near future with this new evidence. If you have any questions, please don't hesitate to reach out.

Regards,



George Hanna
PIC/Owner
1st Choice Pharmacy
Ph: 727-934-1300

# 1st Choice Pharmacy

From:
George Hanna, RPh
1st Choice Pharmacy
2228 US Hwy 19 N
Holiday, FL 34691

To Whom It May Concern:

The application for licensure as a non-resident pharmacy with the state of Arkansas was denied. Per the Arkansas board of pharmacy, approval would be considered pursuant to attendance at a board meeting and explaining certain practices. The practices that were in question are using a lyophilizer, a measurement on a certification report showing that the hazardous room went out of range for the negative pressure, and the compounding of peptides pursuant to legitimate prescriptions. 1st Choice Pharmacy is appealing this decision with Arkansas with these explanations. If you have any questions, please don't hesitate to reach out.

Regards,



George Hanna
PIC/Owner
1st Choice Pharmacy
Ph: 727-934-1300

# 1st Choice Pharmacy

March 24, 2022

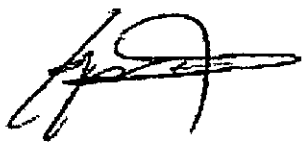
To:
Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201

RE: Denial Letter of Application for Out-of-State Pharmacy License

Dear Mr. Luke Daniel:

This letter serves to notify the Arkansas Board of Pharmacy that Pope Shenouda LLC dba 1st Choice Pharmacy is requesting to appeal this administrative denial of our application pursuant to the Arkansas Administrative Procedures Act, Ark. Code Ann. §25-15-201, et seq. Please let us know when the next available board hearing will be held so that we may appear in person to appeal this decision.

Regards,



George Hanna
1st Choice Pharmacy
2228 US Hwy 19 N
Holiday, FL 34691

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

### Section 1: General Information

Pharmacy Name: Pope Shenouda LLC DBA 1st Choice Pharmacy

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 2228 US HWY 19 N

City: Holiday State: FL Zip: 34691

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 727-934-1300 Toll Free # (NAC 639.708, NRS 639.23286): 844-565-5155

Fax: 727-934-1313 Contact Email: firstchoicepharmacy@yahoo.com

Website: www.1stchoicepharmacy.net

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Joseph Bishay

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23157

Name of Person with direct knowledge of compounding procedures: George Hanna and Joseph Bishay

Email of Person with direct knowledge of compounding procedures: george@1stchoicerx.org, joseph@1stchoicerx.org

Telephone of Person with direct knowledge of compounding procedures: 727-934-1300

**Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)**

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☑ Low ☑ Medium ☑ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☑ Yes ☐ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
see attached

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ☐ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:
For each sterile compound:
1. Method suitability
2. Initial and end sterility and endocrine
3. Potency over time and pH
4. If oilbase no pH over time

SOP 602.4

6. What laboratory performs this additional testing?
Name: Pharmetric Lab
Address: 11880 28th St North Suite #210
City: St. Petersburg State: FL Zip: 33716
Telephone: _____

7. What is your procedure for visual inspection of compounded sterile products?
Visual inspection of drug production

SOP 616.1

8. How often do you perform glove fingertip and medial fill testing?
In the beginning and every 6 months

9. What is your policy if an employee fails a glove fingertip or media-fill test?
SOP 408.4
SOP 402.7

10. Describe your initial and annual training program for all personnel performing sterile compounding:
1. Training and read the SOPs
2. Hand hygiene and garbing (SOP 404)
3. Orientation, training and competency evaluation of compounding personnel (SOP 410)
4. Personal aseptic media fill testing and product verification and related forms (SOP 402)
5. Conduct of personnel in controlled array and aseptic technique overview (SOP 412)
6. Inventory storage, handling and disposal (SOP 502)
7. Use of automated

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
Cleaning in the beginning of the day and the end of the day and beginning of each compound ( immediately prior of each compound)
We use:
Sterile wipes
Sterile peribox (contact time 8 minutes)
Other sterile IPA

Friday- use Decon-phene

12. Who performs the sterile compounding process at your facility?
Pharmacists:George Hanna, Joseph Bishay
Pharmacist Intern: Mina Shenouda
Techs: Dayesi Hernandez, Ileana Ortega

13. Who is responsible and accountable for the sterile compounding process at your facility?
Joseph Bishay
George Hanna

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
For cold products we use warn strip or kangaroo bag

SOP 510

| Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.) | | |
|---|---|---|
| 1. What type of primary engineering controls will you be using in your facility?<br>Biological safety cabinet (ESCO) Class II Type A2 | | |
| 2. Is your BSC or CACI vented 100% to the outside? | ☑ Yes | ☐ No |
| 3. Do you have a negative pressure buffer room at your facility? | ☑ Yes | ☐ No |
| 4. Will you be compounding with antineoplastic HDs or HD API? | ☑ Yes | ☐ No |
| 5. If yes, are the drugs stored in an externally ventilated, negative pressure room? | ☑ Yes | ☐ No |
| 6. Will you be utilizing a closed system transfer device? | ☐ Yes | ☑ No |
| 7. If yes, list the name of the device: | | |
| 8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?<br>Provide patients with packet (attached) | | |
| 9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?<br>1. Orientation, training and competency evaluation of compounding pharmacy personnel (SOP 410)<br>2. Hazardous drug/ risk acknowledgment form (SOP 706.9)<br>3. Competency Assessments<br>- HP inventory receiving (SOP 700.6)<br>- Donning and doffing PPE for HD compounding (SOP 706)<br>- Hazardous drug compounding (SOP 700)<br>- Decontamination, cleaning and disinfection of HD environment (SOP 700) | | |

**Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)**

1. List the specific high risk sterile products that your facility compounds:
see attached

2. What sterilization methods are utilized at your facility?
filtration

3. Does your facility utilize biological indicators? ☐ Yes ☐ No

4. If yes, describe how they are utilized:

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mina Shenouda
Name of Person who Completed the Form

Pharmacist Intern
Title

Mina Shenouda
Signature (copies or stamps not accepted)

12/8/22
Date

| Board Use Only | Date Received:_____ Date Approved: _____ Approved By: _____ |
|---|---|

# Safe Handling of Hazardous Medicines in the Home

Some medicines need special handling because they can be hazardous (harmful) to the people giving them. This is because some studies show that people who care for patients taking these special medicines can also have changes within their own body's cells. These changes can be avoided by following certain steps. Exposure can occur from spills, splashes, breathing in the medicine's vapors or powder, and from coming in contact with the patient's vomit, urine or stool.

The medicine that needs safe handling is:

_____

The risk of danger from handling small amounts of these hazardous medicines is small, but it is a good idea to avoid exposure if possible. Here are suggestions for things you can do at home to limit exposure.

## Supplies you may need

- Disposable gloves (Picture 1) – Get them from your local pharmacy or 1st Choice Compounding Pharmacy
- Disposable gown – if you are handling liquid medicines
- Household soap or detergent – any brand can be used for cleaning
- Disposable towel – in case of an accidental spill
- Two-ply, heavy duty trash bag – for used supplies
- Disposable plastic medicine cups and oral syringes – depending on what kind of medicine is being taken



**Picture 1** Putting on disposable gloves.

- Needle disposal or "sharps" container – needed if you are handling injectable (given by needle or IV) medicines

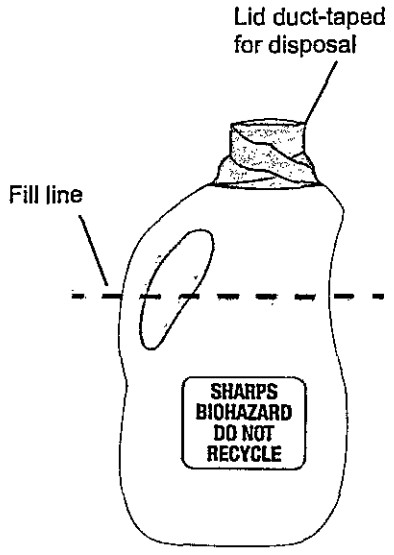
Continued...

## Safety measures for handling hazardous medicines

- Wash your hands **before and after** handling hazardous medicines.
- Use disposable gloves if you are touching any type of hazardous medicine. Do not use torn or punctured gloves.
- Use disposable plastic medicine cups to move a pill from a medicine bottle.
- Throw away any used gloves, gowns, medicine cups, oral syringes, or bottles in a two-ply, heavy-duty trash bag. Tie or seal the plastic bag and place it in your household trash bag for disposal. Be sure to keep this trash out of the reach of pets and children.
- If you are pregnant or trying to become pregnant, you should not handle hazardous medicines. If you are the primary caregiver, speak to your nurse, doctor, or pharmacist about safe ways to care for the patient.

## Handling hazardous medicines at home – needles and sharps

- Do not recap the used needle. Do not bend or break off the needle.
- Do not remove the needle from the syringe.
- All sharps or needles must be thrown away in a safe 'sharps container.' If you do not have a hospital-issued sharps container, use a container made of **heavy-duty plastic. This can be a laundry detergent bottle or liquid laundry softener bottle (Picture 2).** It must close with a lid that screws on tightly. Needles should not be able to poke through (puncture) the lid. The container must be leak-proof, and able to sit up and not fall over (stable).




**Picture 2** Hard plastic laundry detergent bottle and fill line.

- Place the container in the middle of a full, heavy duty trash bag. You are allowed to put the trash bag out for regular trash pick-up. DO NOT put the container in the recycling.

## Storing hazardous medicines

- Your pharmacist or nurse will tell you if there are any special storage instructions.
- Keep all drugs out of reach of children or pets.
- Keep hazardous medicines separate from all other medicines.
- If the medicine needs to be refrigerated, separate it from other foods. Use a separate bin in the refrigerator or place the medicine in a container.
- Keep the hazardous medicine in its original bottle or container. Do not place it in a pill box with other non-hazardous medicines.

## Taking hazardous medicines

- Your physician, nurse, or pharmacist will explain to you how and when to take your medicine.
- It is important for you to take these drugs exactly as told. Do not skip a dose without discussing it with your physician.
- If you forget to take a dose, do not take double the dose the next time. Contact your physician's office or pharmacist to discuss what to do if this happens.

## Accidental hazardous medicine spills

- If you are taking a hazardous medicine and it spills, wear a disposable gown and two pairs of gloves to clean up the spill. Cover the spill with a disposable towel, and then thoroughly wipe up the spill. The area should then be cleaned three times with a home cleaning product. This is to make sure that no medicine is left on the surface. All materials should be thrown away in a heavy-duty sealed trash bag and placed in a trash can that is out of reach of pets and children.
- Hazardous liquid medicines spilled on your skin may cause irritation. Wash the area well with soap and water and dry. If redness or irritation occurs within 7 days, contact your doctor.
- If the drug splashes in the eye, rinse the eye with tap water for at least 15 minutes and contact your doctor.

During clinic visits, be sure to tell the staff about any hazardous drugs you may have taken at home. If you have any other questions or concerns, ask your doctor, pharmacist, or nurse.

1. Testosterone cypionate 200mg/ml in sesame oil 5ml intramuscular
2. Testosterone enanthate 200mg/ml in sesame oil 5ml intramuscular
3. Cyanocobalamin 1200mcg/ml 10ml intramuscular
4. Nandrolone decanoate 200mg/ml 5ml intramuscular
5. Methionine/inositol/choline/cyanocobalamin 25mg/100mg/50mg/1mg /ml 10ml intramuscular
6. Methionine/inositol/choline/L-carnitine/cyanocobalamin 25mg/25mg/50mg/100mg/1mg /ml 10ml intramuscular
7. L-leucine/isoleucine/valine 10mg/10mg/5mg/ml 10ml intramuscular
8. Vitamin D3 50000 iu/ml in sesame oil 5ml intramuscular
9. Testosterone cypionate/testosterone enanthate 160mg/40mg/ml in sesame oil 5ml intramuscular
10. Ascorbic acid 550mg/ml 10ml intramuscular

High Risk Preparations

1. Testosterone cypionate 200mg/ml in sesame oil 5ml intramuscular
2. Testosterone enanthate 200mg/ml in sesame oil 5ml intramuscular
3. Testosterone cypionate/testosterone enanthate 160mg/40mg/ml in sesame oil 5ml intramuscular
4. BPC-157 15mg injection
5. Ipamorelin 15mg injection
6. Ipamorelin/sermorelin 15mg/15mg injection
7. Ipamorelin/CJC-1295 15mg/6mg injection
8. Sermorelin 15mg injection
9. Bremelanotide 20mg injection
10. Bremelanotide 2mg/ml nasal spray
11. AOD-9604 nasal spray 200mcg/0.1ml
12. AOD-9604 RDT 500mcg

# STATE OF FLORIDA
# DEPARTMENT OF HEALTH
# INVESTIGATIVE SERVICES
## INV359 - Community Requirements

File # 15765
Insp # 175881

| NAME | PERMIT NUMBER | DATE OF INSPECTION |
|---|---|---|
| POPE SHENOUDA, LLC | 23208 | 04/28/2022 |
| **DOING BUSINESS AS** | | |
| 1ST CHOICE PHARMACY | | |
| **STREET ADDRESS** | **TELEPHONE #** | **EXT** |
| 2228 US Hwy 19 | 727-934-1300 | |
| **CITY** | **COUNTY** | **STATE/ZIP** |
| HOLIDAY | PASCO | FL/34691 |

### Additional Information

**Business Operation Hours**

| | |
|---|---|
| M-T-W-TH-F N | Weekly Hours |
| Monday Y | Monday Hours 9:00 AM TO 6:30 PM |
| Tuesday Y | Tuesday Hours 9:00 AM TO 6:30 PM |
| Wednesday Y | Wednesday Hours 9:00 AM TO 6:30 PM |
| Thursday Y | Thursday Hours 9:00 AM TO 6:30 PM |
| Friday Y | Friday Hours 9:00 AM TO 6:30 PM |
| Saturday N | Saturday Hours 10:00 AM to 1:00 PM |
| Sunday N | Sunday Hours CLOSED |

**Registered Pharmacist / Intern / Tech**

| | |
|---|---|
| License # PS 40421 | Licensee Name George Amin Hanna, PDM |
| License Type Registered Pharmacists | |
| License # RPT 68132 | Licensee Name Dayesi Hernandez, Compounding technician |
| License Type Pharmacy Tech | |
| License # PSI | Licensee Name Mina Shenouda, Compounding intern |
| License Type Intern | |
| License # RPT76680 | Licensee Name Natashia Medina, Data entry |
| License Type Pharmacy Tech | |

**ACS Manager**

| | |
|---|---|
| | |

**Optional Information**

| | |
|---|---|
| | |

**Basic License Data - PSD**

| | |
|---|---|
| DEA Reg # FP0721123 | |

### License Relations

**Pharmacy Affiliate**

| | |
|---|---|
| HANNA, GEORGE AMIN | License # |

**RX DPT MGR/COR/POR**

| | |
|---|---|
| HANNA, GEORGE AMIN | License # 40421 |

**Special Sterile Compounding**

| | |
|---|---|
| POPE SHENOUDA LLC | License # 29868 |

## INV 359 - Community Requirements

**Signage Requirements Section**

# INV359 - Community Requirements

Insp # 175881

POPE SHENOUDA, LLC

File # 15765

| | |
|---|---|
| Signage stating the hours the pharmacy department is open. [64B16-28.1081 (2) F.A.C.]<br>*But a sign dated 6/14/21 stated "The retail department will be at the pharmacy located across the plaza"* | Yes |
| A sign with bold letters not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons stating, "Prescription Department Closed". [64B16-28.109 F.A.C.] | N/A |
| Patient Consultation Area sign is posted. [64B16-30.003, F.A.C]<br>*No patient consultation sign noted. It was posted during the inspection.* | No |

**Community Requirements General Section**

| | |
|---|---|
| Expired medications removed from the shelves. [64B16-28.110 F.A.C.]; [64B16-28.1191 F.A.C.] | Yes |
| Rx Department is open for a minimum of 20 hours per week. [64B16-28.1081 (1) F.A.C.] | Yes |
| All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c) F.S.]; [21CFR1306.05] | Yes |
| Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)]; [64B16-28.140(3)(d) & F.A.C]<br>*Not signed by compounding pharmacist GH who verifies compounding in PK on dates these were signed off in PK* | No |
| Prescription department has current copy of laws and rules, references and equipment necessary to the professional practice of pharmacy. [64B16-28.102 F.A.C.] | Yes |
| Pharmacy technicians and interns properly identified and supervised [64B16-27.100 (2) F.A.C.]; [64B16-27.4001 F.A.C.]; [64B16-27.410 F.A.C.]; [64B16-27.420 F.A.C.]. | Yes |
| Legend drugs properly stored. [64B16-28.118 F.A.C.]; [64B16-28.120 F.A.C.] | Yes |
| Documentation of destruction of controlled substances. [64B16-28.303, F.A.C.]<br>*Rx Return Solutions 6/21/21* | Yes |
| Generic equivalent sign is posted. [465.025(7), F.S] | Yes |

**Additional Community Requirements**

| | |
|---|---|
| Prescription department is clean and safe, has a sink with running water convenient to the prescription department. [64B16-28.102 F.A.C.] | Yes |
| Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.] | Yes |
| When a pharmacist is not on duty, the prescription department is securely locked, and no other personnel remain in the department. [64B16-28.109 F.A.C.] | N/A |
| Written policy and procedure manual regarding the number of technician positions and their utilization. [64B16-27.410(2) (a), F.A.C.] | Yes |
| Documentation signed by Pharmacy technician acknowledging review of the Policy and Procedure manual within 90 days of hire. [64B16-27.410(2) (b), F.A.C.] | Yes |
| Documentation that Pharmacy technician has been trained in the established job description. [64B16-27.410(2)(c), F.A.C.] | Yes |
| Pharmacy licenses are current. [465.015(1)(a) F.S.] | Yes |
| Private consultation area available [6416-28.1035 F.A.C.] | Yes |
| Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]<br>*There is no written offer to counsel patients of other states.* | No |
| Medication properly labeled. [499 F.S.]; [64B16-28.108 F.A.C.]; [893.04(1)(e) F.S.] [21CFR1306.24]; [21CFR1306.14]<br>*Several vials such as Myers Cocktail do not contain the Federal Legend, specifically lot 04252022@5 or Magnesium Chloride/Taurine compound lot 03232022@19. These are dymo labeled drugs due to lack of extended BUD and the amount of ingredients listed. These vials were noted to have black and white labels.* | No |
| Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and summarization of Quality-Related Events which have been reviewed by the CQI committee quarterly are available for inspection. [64B16-27.300 F.A.C.]; [766.101(1)(a)(l) F.S.]<br>*2-21-22, 11/26/21, 8/2/21, 5/4/21.* | Yes |
| Policy and Procedure available and implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.] | Yes |
| Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]<br>*Maintained in PK and Life file and formerly Prime rx.* | Yes |
| Written prescriptions for controlled substances are on counterfeit-proof pads from Department-approved vendors. [893.065 F.S.]; [456.42(2) F.S.]<br>*Mostly e-prescribed* | Yes |
| Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a) F.S.]; [21CFR1304.11]<br>*The pharmacy only has CIII to CV controlled substances documented on biennial inventory from 6-14-22, however has not included CII's sold to MMG Pharma LLC dba Cross Pharmacy at 2208 US Highway 19 N, Holiday. Not documented whether inventory was taken at open or close of business.* | No |
| DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2) F.S.]; 21CFR 1305.13(e)]; [21CFR1305.22(g)]<br>*CSOS with Amerisource Bergen* | Yes |
| Controlled substance records and Rx information in computer system are retrievable. [21CFR1304.04]; [465.022(12) (a) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.] | Yes |
| Controlled substance records are maintained for 4 years [465.022(12) (b) F.S.] [64B16-28.140 F.A.C.]<br>*Pharmacy has sold one time inventory to MMG Pharma 6/14/21.* | Yes |
| Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.] | N/A |
| Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b) F.S.]; [465.022(11) (b) F.A.C.] | N/A |
| Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4) (3)(a), F.S.] | Yes |
| Compounding records properly maintained. [64B16-28.140(4), F.A.C.]<br>*See comments on sterile compounding Inspection.* | No |
| The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005 F.S.] [61N-1.012 F.A.C.] | Yes |

# INV359 - Community Requirements

Insp # 175881 POPE SHENOUDA, LLC File # 15765

| | |
|---|---|
| Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005 (14) F.S.]<br>*Wholesalers: Amerisource Bergen, Cardinal, River City, Masters Pharmaceutical, Medisca, PCCA, Spectrum.* | Yes |
| Administration begins not later than 1 hour following start of immediate use CSPs preparation. [64B16-27.797 F.A.C.] | N/A |
| Facility engaged in non-sterile office use compounding for human use is registered with FDA as an outsourcing facility [F.A.C 64B16-27.700(3)(g)] | N/A |
| Signage indicating that any patient receiving testing, screening, or treatment services is advised to seek followup care from his or her primary care physician. [465.1895 (9) F.S.] | N/A |
| Pharmacist has a written collaborative practice agreement. [465.1865, F.S.] | N/A |
| Human Trafficking signage is posted in a conspicuous place accessible to employees that is at least 11 inches by 15 inches in size, printed in a clearly legible font and in at least a 32-point type which gives instructions in English and Spanish on how to report to the National Human Trafficking Resource Center. [456.0341, F.S] | Yes |

**Pharmacy Ships Medicinal Drugs to Patients [ 64B16-28.10801, F.A.C]**

| | |
|---|---|
| Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent.<br>*See SOP 510 "Packaging and Shipping of Refrigerated Drug Products"*<br>*Reviewed Kangaroo mailer study.*<br>*The SOP does not address shipments of medicinal drugs to other states. The pharmacy is licensed in greater than 37 states* | Yes |
| Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs. | Yes |

**Pharmacy engages in Centralized Prescription Filling? [64B16-28.450, F.A.C.]**

| | |
|---|---|
| Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy.<br>*Pharmacy does not have a mutual agreement with Trinova, Trinova being the originating pharmacy for prescriptions for compounds.* | No |
| Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions.<br>*Not available during inspection* | No |
| The originating pharmacy is identified with pharmacy name and address on the prescription container label.<br>*Not on label, but originating pharmacy Trinova Health stated on e-prescription.* | No |
| The central fill pharmacy is identified by name and address or a by a code available at the originating pharmacy. | N/A |
| If a controlled substance, the word "central fill" appears on the face of the original prescription.<br>*Original prescription sent by Trinova Health does not contain the word "Central fill" see rxC514455,* | No |
| The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy's employee accepting delivery.<br>*This pharmacy is the central fill pharmacy who directly mails it to the patient.* | N/A |

**Automated Pharmacy System [465.0235, F.S.]**

| | |
|---|---|
| Pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling. | |
| Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years. | |

**Internet Pharmacy**

| | |
|---|---|
| A toll-free telephone number is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. [465.0197 (3)(e), F.S.] | |
| Toll free number is disclosed on the label affixed to each container of dispensed medicinal drugs. [465.0197 (3)(e), F.S.] | |
| Documentation of a valid, unexpired pharmacy license, permit or registration in the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed. [465.0197(3)(a) F.S] | |

## Remarks:

Pharmacy at this location has Life File and PK software and Prime rx. PDM states this retail establishment has been sold to MMG Pharma LLC dba Cross Pharmacy at 2208 US 19N however retail permit is still maintained at 2228 US Hwy 19, Holiday, FL for non-sterile compounding.
The closed system pharmacy PH30309 was moved to 2049 Welbilt Blvd and is operating under A&Eof Tampa Bay LLC, dba 1st Choice LTC Pharmacy, Suite A.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Inspector Signature

CULLIPHER, MALA

Date:4/28/2022

Representative:

George Hanna

Date:4/28/2022

# STATE OF FLORIDA
# DEPARTMENT OF HEALTH
# INVESTIGATIVE SERVICES
## INV797-Sterile Compounding

File # 22731
Insp # 178092

| NAME | PERMIT NUMBER | DATE OF INSPECTION |
|---|---|---|
| POPE SHENOUDA LLC | 29868 | 04/28/2022 |
| **DOING BUSINESS AS** | | |
| 1ST CHOICE COMPOUNDING PHARMACY | | |
| **STREET ADDRESS** | **TELEPHONE #** | **EXT** |
| 2228 2228 U. S. HWY 19 N | (727) 934-1313 | |
| **CITY** | **COUNTY** | **STATE/ZIP** |
| HOLIDAY | PASCO | FL/34691 |

**Additional Information**

**Business Operation Hours**

| | |
|---|---|
| M-T-W-TH-F N | Weekly Hours |
| Monday Y | Monday Hours 9 AM TO 6:30 PM |
| Tuesday Y | Tuesday Hours 9 AM TO 6:30 PM |
| Wednesday Y | Wednesday Hours 9 AM TO 6:30 PM |
| Thursday Y | Thursday Hours 9 AM TO 6:30 PM |
| Friday Y | Friday Hours 9 AM TO 6:30 PM |
| Saturday Y | Saturday Hours 10 AM TO 2 PM |
| Sunday N | Sunday Hours CLOSED |

**Registered Pharmacist / Intern / Tech**

| | |
|---|---|
| License # PS40421 | Licensee Name George Hanna, PDM |
| License Type Registered Pharmacists | |
| License # RPT57866 | Licensee Name Natasha Medina, Data Entry |
| License Type Pharmacy Tech | |
| License # PSI30754 | Licensee Name Mina Shenouda Meawad Shenouda |
| License Type Intern | |
| License # RPT68132 | Licensee Name Dayesi Hernandez, Sterile HD technician |
| License Type Pharmacy Tech | |
| License # RPT93349 | Licensee Name Mary Hanna, Sterile Non-HD |
| License Type Pharmacy Tech | |
| License # PS54381 | Licensee Name Joseph Bishay, Sterile Dispensing Pharmacist |
| License Type Registered Pharmacists | |
| License # RPT17049 | Licensee Name Sean K Francisco, IT |
| License Type Pharmacy Tech | |
| License # PS61576 | Licensee Name Sylvia George Abdelmessih Makar Faltous, Initial Verification Life File |
| License Type Registered Pharmacists | |
| License # RPT96882 | Licensee Name Ereny Fakhry Abdelmalik, Filling technician |
| License Type Pharmacy Tech | |

**ACS Manager**

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|---|---|
| | |

**Optional Information**

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| | |

**Basic License Data - PSD**

| | |
|---|---|
| DEA Reg # FP0721123 | |

**License Relations**

**Pharmacy Affiliate**

# INV797-Sterile Compounding

Insp # 178092 | POPE SHENOUDA LLC | File # 22731

| | |
|---|---|
| HANNA, GEORGE AMIN | License # |

**RX DPT MGR/COR/POR**

| | |
|---|---|
| HANNA, GEORGE AMIN | License # 40421 |

**Special Sterile Compounding**

| | |
|---|---|
| POPE SHENOUDA, LLC | License # 23208 |

## INV797 - Sterile Compounding

### LOW RISK

| | |
|---|---|
| 1. Low risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and no more than two entries into any container. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs] | |
| 2. Low Risk CSP's, in absence of passing sterility test, stored not more than 48 hours at controlled room temperature, 14 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs] | |
| 3. Low Risk CSP's with 12 hour BUD are properly identified and comply with all four specific criteria. 1. PEC in Segregated Compounding area 2. Away from windows, doors , high traffic areas 3. Hygiene & garbing required, sinks not adjacent to PEC. 4. Cleaning & Disinfecting, Personnel training, Competency evaluation, Garbing, Aseptic work practices, Viable and non-viable environmental sampling apply. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Low-Risk Level CSPs] | |

### MEDIUM RISK

| | |
|---|---|
| 4. Medium Risk CSP's are properly identified: Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs] | |
| 5. Medium Risk CSP's, in absence of passing sterility test, stored not more than 30 hours at controlled room temperature, 9 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs] | |

### HIGH RISK

| | |
|---|---|
| 6. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in no worse than an ISO Class 8 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas] | Yes |
| 7. High Risk CSP's are properly identified: Confirmed presence of nonsterile ingredients and devices, or confirmed or suspected exposure of sterile ingredients for more than one hour to air quality inferior to ISO Class 5 before final sterilization. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]<br>*Pharmacy compounds Peptides in the ISO 5 HD BSC where the lyophilizer is attached. The pharmacy no longer compounds Trimix or Alprostadil stock solution based on records provided.* | Yes |
| 8. High Risk CSP's, in absence of passing sterility test are not stored more than 24 hours at controlled room temperature, 3 days at cold temperature, or 45 days in solid frozen state at -25° to -10° or colder. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs] | Yes |
| 9. A 0.2-µm certified sterilizing membrane filter is used that is chemically and physically compatible with the CSP. Filtration is completed rapidly without filter replacement. Sterilization method is verified to achieve sterility for the quantity and type of containers. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration]<br>*Sterilizing filter MDI Aseptipcap is not capable of accomodating 5 L volume.* | Yes |
| 10. Sterilization method used has documentation that acceptable strength and purity of ingredients and integrity of containers is maintained. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs] | Yes |
| 11. The manufacturer recommended filter integrity (e.g., bubble point) test is performed and documented for all sterilizing filters after filtering CSPs. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Filtration] | Yes |
| 12. Autoclave cycle has been verified using appropriate biological indicators. Solutions are passed through a 1.2-µm or smaller filter into final containers to remove particulates before sterilization. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Steam]<br>*Tuttnauer Autoclave Steam Sterilizer SN 21030347 study demonstrates temp of 121 C duration 30 mins, dry times 60 mins-validated by Pharmetric April 1, 2022.*<br>*Pharmacy autoclaves rubber stoppers, flip caps, mop cover and foam beds (pre use) then discards mop cover. BI's are 3M Attest. Autoclave not used to terminally sterilitze CSP's.* | Yes |
| 13. Dry heat ovens used for sterilization have filtered forced air. Only those items that will be damaged by steam are sterilized by dry heat. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat]<br>*Dry Heat oven does have filtered forced air. Pharmacy does not terminally sterilize solutions in the dry heat oven. Oven is used to sterilize beakers with stirrers, vials.* | N/A |
| 14. The description of dry heat sterilization conditions and duration for specific CSPs is included in written documentation in the compounding facility. The effectiveness of dry heat sterilization is verified using appropriate biological indicators and other confirmation. [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Sterilization of High-Risk Level CSPs by Dry Heat] | N/A |
| 15. Dry heat depyrogenation is used to render glassware or containers, such as vials free from pyrogens as well as viable microbes. The description of the dry heat depyrogenation cycle and duration for specific load items is included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle is verified using endotoxin challenge vials (ECVs). [VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY : Depyrogenation by Dry Heat]<br>*Pharmetric Dry Heat Oven validated Nov 2, 2021 with Endosafe cartridges to demonstrate a 6.1 log reduction in ET* | Yes |
| 16. Sterility testing is completed for all High-risk level CSPs prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8° before being sterilized. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing] | Yes |

### USP <71> STERILITY TESTING (Outsourced)

| | |
|---|---|
| 17. Outsourced sterility testing results indicate that it is compliant with USP<71>. A method not described in the USP may be used if validation demonstrates that the alternative is at least as effective and reliable. [STERILITY TEST USP<71>] | Yes |
| 18. Outsourced: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested] | Yes |
| 19. Outsourced: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested] | Yes |

# INV797-Sterile Compounding

Insp # 178092 — POPE SHENOUDA LLC — File # 22731

| | |
|---|---|
| 20. Outsourced: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test]<br>*Hercules compound has undergone method suitability-23 vials were compounded on 2-18-2022* | Yes |
| 21. Outsourced: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS] | Yes |

**USP <71> STERILITY TESTING**

| | |
|---|---|
| 22. On site: Membrane filtration is used if appropriate. (The technique of membrane filtration is used whenever the nature of the product permits; that is, for filterable aqueous preparations, for alcoholic or oily preparations, and for preparations miscible with, or soluble in, aqueous or oily solvents, provided these solvents do not have an antimicrobial effect in the conditions of the test.) Filters are rinsed according to USP<71>. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing] | |
| 23. On site: Direct inoculation is done only when membrane filtration cannot be carried out. Volume to be inoculated does not exceed 10% of the culture media volume. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Sterility Testing] | |
| 24. On site: The number of articles tested are appropriate according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested] | |
| 25. On site: The volume/quantity tested is according to USP<71>. [STERILITY TEST USP<71> : Number of Articles to Be Tested] | |
| 26. On site: A growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP<71>. [STERILITY TEST USP<71> : Growth Promotion Test of Aerobes, Anaerobes, and Fungi] | |
| 27. On site: A USP<71> method suitability test has been done with appropriate inoculum, additives and rinses. [STERILITY TEST USP<71> : Method Suitability Test] | |
| 28. On site: TSB or SCD is incubated at 20-25 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures] | |
| 29. On site: FTM is incubated at 30-35 C for 14 days (2 incubators present). [STERILITY TEST USP<71> : Culture Media and Incubation Temperatures] | |
| 30. On site: Sterility testing is documented including lot numbers and expiration dates of media. [FINISHED PREPARATION RELEASE CHECKS AND TESTS] | |
| 31. On site: Sterility testing reports are reviewed and appropriate actions taken and documented. [FINISHED PREPARATION RELEASE CHECKS AND TESTS] | |

**ENDOTOXIN TESTING**

| | |
|---|---|
| 32. Endotoxin testing is conducted for High-risk level CSP's that are prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized or in multidose containers for administration to multiple patients. (excluding those for inhalation and ophthalmic administration) [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing]<br>*Done by Pharmetric* | Yes |
| 33. Endotoxin testing process indicates that it is compliant with USP<85>. [BACTERIAL ENDOTOXINS TEST USP<85>] | Yes |
| 34. High Risk CSP's are within allowable limits for bacterial endotoxins. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Bacterial Endotoxin (Pyrogen) Testing] | Yes |

**IMMEDIATE USE COMPOUNDING**

| | |
|---|---|
| 35. Immediate-use compounding complies with all six specified criteria. 1. Low-risk sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers. Anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs.<br>2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour.<br>3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces.<br>4. Administration begins not later than 1 hour following the start of the preparation of the CSP.<br>5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time.<br>6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded. [IMMEDIATE-USE CSPs] | N/A |

**SINGLE/MULTIPLE DOSE CONTAINER BUD**

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| 36. Beyond-use date does not exceed 28 days for multiple-dose containers after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS] | N/A |
| 37. Beyond-use time does not exceed 6 hours for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry, unless specified otherwise by the manufacturer. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS] | Yes |
| 38. Beyond-use time does not exceed 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS] | N/A |
| 39. Single-dose ampules are discarded immediately after use. [SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS] | N/A |

**HAZARDOUS DRUGS**

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| 40. A pressure indicator is installed and differential pressures are monitored and documented daily for hazardous buffer room. [HAZARDOUS DRUGS AS CSPs] | Yes |
| 41. Hazardous drug buffer room is at least 0.01 inch water column negative pressure with 30 ACPH of HEPA filtered air. [HAZARDOUS DRUGS AS CSPs]<br>*Per MTA Feb 15, 2022 report, ACPH documented for negative sterile buffer room was 38* | Yes |
| 42. At least 0.01 inch water column negative pressure and 12 air changes per hour in non-cleanrooms in which CACIs are located. FAC: USP Chapter 797 requires that: "When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within an ISO Class 5 environment of a BSC or CACI. The use of the CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable." For purpose of said provision, a "low volume of hazardous drugs" is defined as less than 40 doses per month. [HAZARDOUS DRUGS AS CSPs] | N/A |
| 43. Personnel compounding hazardous drugs wear appropriate personal protective equipment. [HAZARDOUS DRUGS AS CSPs] | Yes |

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| 44. Hazardous drugs are handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparing for administration, and disposal. Spill kits are available. [HAZARDOUS DRUGS AS CSPs]<br>*Using BioClean Emerald Sterile Nitrile Cleanroom Gloves rated to handle HD's.* | Yes |
| 45. Hazardous drugs are prepared in an ISO Class 5 environment (BSC or CACI) with protective engineering controls in place, following aseptic practices specified for the appropriate contamination risk levels. [HAZARDOUS DRUGS AS CSPs]<br>*HD's such as Testosterone and Nandrolone compounded in the same BSC where Peptides such as Semaglutide, Sermorelin, Ipamorelin and CJC combinations are compounded. These HD's may pose a risk of contamination to the non-HD peptide where partially stoppered vials are lyophilized over several hours and then removed and crimped in the BSC. The pharmacy is decontaminating the BSC after each batch with Peridox.* | No |
| 46. Hazardous drugs are stored separately from other inventory in a manner to prevent contamination and personnel exposure. [HAZARDOUS DRUGS AS CSPs] | Yes |
| 47. Access to hazardous drug preparation areas is limited to authorized compounding personnel. [HAZARDOUS DRUGS AS CSPs] | Yes |
| 48. Annual documentation of hazardous drug training of personnel regarding storage, handling, containment techniques and disposal of hazardous drugs is available. [HAZARDOUS DRUGS AS CSPs]<br>*Critical Point* | Yes |
| 49. Compounding personnel of reproductive capability have confirmed in writing that they understand the risks of handling hazardous drugs. [HAZARDOUS DRUGS AS CSPs]<br>*No risk attestation for HD compounding -JB- he is currently under training.* | Yes |
| 50. Facility maintains appropriate disposal containers for all hazardous waste. [HAZARDOUS DRUGS AS CSPs] | Yes |

**FACILITY DESIGN AND CERTIFICATION**

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| 51. Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) have been performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Corrective action for deficiencies are documented. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) are conducted under dynamic conditions. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Nonviable Particle Testing Program]<br>*MTA certification Feb 15, 2022, Aug 9, 2021*<br>*MTA Feb 2, 2021 and Aug 13, 2020 for positive pressure cleanroom,*<br>*SEC's: Ante room ISO 8, IV buffer room ISO 7, PEC's: Air Clean Systems HLF-1432 AC6000HLF-1432 ISO 5*<br>*Pass-through #2 ISO 8 (anteroom to non-HD buffer room), Buffer room pass through (ISO 7) Sink (ISO 8)*<br>*HD cleanroom*<br>*HD SEC's: ISO 7 anteroom, negative pressure IV buffer room certified as ISO 7*<br>*HD PEC: Esco Class II A2 BSC-142292 SN 2019-142292 certified as ISO 5*<br>*HD room has a built in Lyophilizer SP Scientific model ADP-C2-S2EL-EVA-X SN 325488 (certified as ISO 5 in Feb 2022)*<br>*Ante room Pass through certified as ISO 7* | Yes |
| 52. Primary engineering controls provide unidirectional (i.e., laminar) HEPA filtered air. Air pattern analysis via smoke studies are conducted at the critical site to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.[ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]<br>*Smoke studies performed in the BSC with the lyophilizer attached to the right of the hood under dynamic operational conditions but lacking a demonstration showing completely covered skin as partially stoppered vials inside BSC are transferred to the lyophilizer in the contiguous ISO 5 environment in the HD room.* | Yes |
| 53. The primary engineering controls are placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation. The PEC is placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross drafts. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] | Yes |
| 54. All HEPA filters are leak tested after installation and every six months thereafter. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]<br>*Feb 15, 2022-Hepa Filter #1 and #2 in ante room, Hepa filter #1 for non-HD room with no leaks, HD cleanroom with 1 ante room Hepa filter and 1 IV room*<br>*hepa filter without leaks. PEC Hepa filters also demonstrated no leaks* | Yes |

**ISOLATORS**

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| 55. CAIs are proven to maintain ISO Class 5 air when particle counts are sampled 6 to 12 inches upstream of critical site exposure areas during performance of normal inward and outward transfer of materials, and compounding manipulations when such CAIs are located in air quality worse than ISO Class 7. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas] | |
| 56. Adequate recovery time for isolators to achieve ISO Class 5 air quality is allowed after material transfer before and during compounding operations. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas] | |
| 57. Personnel garbing requirements are followed for CAIs unless manufacturer provides written documentation based on validated testing that any components of PPE are not required to maintain sterility of CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] | |

**FACILITY DESIGN AND CERTIFICATION (Secondary Engineering Controls)**

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| 58. Facility has pressure gauges or velocity meters to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area. The results are reviewed and documented on a log at least daily or by a continuous recording device. The pressures differentials meet or exceed 5 Pa (0.02 inch water column (w.c.)). Alternatively, in facilities where low- and medium-risk level CSPs are prepared, differential airflow is maintained at a minimum velocity of 0.2 meter/second (40 fpm) across a line of demarcation between buffer area and ante-area. [ENVIRONMENTAL QUALITY AND CONTROL : Pressure Differential Monitoring] | Yes |
| 59. Clean rooms for nonhazardous and nonradioactive CSPs are supplied with HEPA filtered air that enters from ceilings with return vents low on walls, and that provides not less than 30 air changes per hour or qualifies for exception in 64B16-27.797(4)(c). [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]<br>*IV Buffer room ACPH documented as 51 from Feb 15, 2022.* | Yes |
| 60. Activities and tasks carried out within the buffer area are limited to only those necessary when working within a controlled environment. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] | Yes |
| 61. Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed are brought into the buffer room. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] | Yes |
| 62. Surfaces and essential furniture in buffer rooms or zones and clean rooms are nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]<br>*Peridox applied in pass through of non-HD IV room did not remove stain or residue in the center of the pass-through, some screws still noted to be discolored and rusted on rivets/threshold in between the ante area and buffer room. The rusty nail was fixed during the inspection as well as threshold cleaner. There is a cart with slightly rusted legs visible and somewhat comes off when wiped off. Cleanroom has ledges in this modular unit-ledges are not recommended by USP.* | No |

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| 63. The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area are smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] | Yes |
| 64. Ceiling tiles are caulked around each perimeter and to walls to seal them to the support frame. The exterior lens surface of ceiling lighting fixtures is smooth, mounted flush, and sealed. All other penetrations through the ceiling or walls are sealed. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls]<br>*Ceiling tiles sealed and caulked* | Yes |
| 65. The buffer area does not contain sources of water (sinks) or floor drains. Work surfaces are constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] | Yes |
| 66. Storage shelving, counters, cabinets and carts/casters in the buffer area are smooth, impervious, free from cracks and crevices, non-shedding, non-porous, cleanable, and disinfectable. [ENVIRONMENTAL QUALITY AND CONTROL : Facility Design and Environmental Controls] | Yes |
| 67. When devices (e.g., computers and printers) and objects (e.g., carts and cabinets) are placed in buffer areas, air quality is verified by particle counts on certification. [ENVIRONMENTAL QUALITY AND CONTROL : ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas]<br>*Repeater pump placed outside the hood.* | Yes |

**QUALITY AND CONTROL**

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| 68. An appropriate environmental sampling plan has been developed for airborne viable particles based on a risk assessment of compounding activities performed. Volumetric air sampling is conducted every six months and sites include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes). The plan includes sample locations, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels. [ENVIRONMENTAL QUALITY AND CONTROL : Environmental Viable Airborne Particle Testing Program—Sampling Plan]<br>*VAS conducted by MTA Feb 15, 2022, Aug 9, 2021.* | Yes |
| 69. Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments is performed by properly trained individuals for all compounding risk levels. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling]<br>*Feb 15, 2022* | Yes |
| 70. Volumetric air sampling using malt extract agar (MEA) or some other media that supports the growth of fungi is used in high-risk level compounding environments. [ENVIRONMENTAL QUALITY AND CONTROL : Growth Media] | Yes |
| 71. For low-risk level CSPs with 12-hour or less BUD, air sampling is performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO class 5 environment. [ENVIRONMENTAL QUALITY AND CONTROL : Viable Air Sampling] | N/A |
| 72. The number of discrete colonies of microorganisms is counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring are transformed into cfu/cubic meter of air and evaluated for adverse trends. [ENVIRONMENTAL QUALITY AND CONTROL : Incubation Period]<br>*Trended by MTA for air and surface samples every 6 months* | Yes |
| 73. Surface sampling is accomplished in all ISO classified areas on a periodic basis using TSA contact plates with lecithin and polysorbate 80 and/or swabs and is done at the conclusion of compounding. [ENVIRONMENTAL QUALITY AND CONTROL : Surface Cleaning and Disinfection Sampling and Assessment]<br>*Pharmacy does monthly surface sampling.* | Yes |
| 74. Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation]<br>*Policy on surface sampling states 1st choice to conduct ss with every single compound.* | Yes |
| 75. Competent microbiology personnel are consulted if an environmental sampling consistently shows elevated levels of microbial growth. If any mold, yeast, coagulase positive staphylococcus, or gram negative rods are detected immediate remediation and investigation into the cause and source was conducted. [ENVIRONMENTAL QUALITY AND CONTROL : Action Levels, Documentation and Data Evaluation] | N/A |
| 76. Surfaces in the LAFWs, BSCs, CAIs, and CACIs are cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] | Yes |
| 77. Cleaning and disinfecting occurs before compounding is performed. Items are removed from all areas to be cleaned, and surfaces are cleaned by removing loose material and residue from spills, e.g., water-soluble solid residues are removed with Sterile Water and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% IPA, which is allowed to dry before compounding begins. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] | Yes |
| 78. Cleaning and disinfecting agents and methods of application are in accordance with written SOPs and followed by custodial and/or compounding personnel. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]<br>*Daily cleaning log reviewed -demonstrates Hyp-chlor followed by Peridox RTU and SIPA, however documents show hypochlor is used, but none in cleanroom, Decon spore used. Each PEC is listed and Lyophilizer listed. Cleaning documentation -procedure does not match policy.* | No |
| 79. Cleaning materials, such as wipes, sponges, and mops, are non-shedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and are not removed from these areas except for disposal. If cleaning materials are reused (e.g., mops), there are procedures based on manufacturer recommendations that ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]<br>*Mop covers from Contec and foam are sterilized using the autoclave* | Yes |
| 80. Supplies and equipment removed from shipping cartons are wiped with a suitable disinfecting agent (e.g., sterile 70% IPA). [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] | Yes |
| 81. Disinfectant sprayed or wiped on a surface to be disinfected is allowed to dry, and during this time the item is not be used for compounding purposes. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] | Yes |
| 82. Sterile 70% IPA pads are used to disinfect the sterile entry points of packages and devices. Wetted gauze pads or other particle-generating material are not appropriate. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] | Yes |

**QUALITY AND CONTROL (Secondary Engineering Controls)**

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| 83. Work surfaces in ISO Class 7 and 8 areas and segregated compounding areas are cleaned at least daily. IPA (70% isopropyl alcohol) remains on surfaces to be disinfected for at least 30 seconds before such surfaces are used to prepare CSPs. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] | Yes |
| 84. Floors in ISO Class 7 and 8 areas are mopped daily by trained personnel at a time when no aseptic operations are in progress using approved agents and procedures described in written SOP's. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] | Yes |

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| 85. Shelving, walls, and ceilings in ante-areas and buffer areas are cleaned and disinfected at least monthly. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]<br>*For months of Feb, used Peridox and SIPA, however, only documented a disinfecting agent for monthly cleaning using Decon-Ahol and IPA* | No |

**PERSONNEL CLEANSING, GARBING & COMPETENCY EVALUATION**

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| 86. Personnel preparing CSP's are free from rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infections. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] | Yes |
| 87. Compounding personnel remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] | Yes |
| 88. Facility has adequate supplies to meet PPE requirements of USP<797>. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] | Yes |
| 89. Garbing and hand hygiene are accomplished in the ante-area in order of dirtiest to cleanest: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying; non-shedding gown. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]<br>*Nail cleansers inside sealed brush/sponge kit* | Yes |
| 90. Sterile gloves are donned in the buffer room/isolator after hand cleansing with an alcohol-based product with persistent activity and hands are allowed to dry. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing]<br>*Non HD cleanroom-Purell Waterless Surgical Scrub, HD cleanroom: Avagard donned prior to donning sterile gloves.* | Yes |
| 91. Gloves are routinely disinfected with sterile 70% IPA after contacting nonsterile objects. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] | Yes |
| 92. Personnel repeat garbing and hand hygiene after they are exposed to direct contact contamination or worse than ISO Class 8 air. Gowns may be hung in the anteroom and reused during the same workshift. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Cleansing and Garbing] | N/A |
| 93. Low/Medium Risk media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding are completed at least annually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : Medium-Risk Level CSPs] | N/A |
| 94. High Risk Media-fill tests that closely simulate the most challenging or stressful conditions encountered during compounding have been completed at least semiannually by compounding personnel. Media-filled vials are appropriately incubated for 14 days. [CSP MICROBIAL CONTAMINATION RISK LEVELS : High-Risk Level CSPs]<br>*JB completed media fill 4/20/22 (still incubating) representing HD lyo. Inspector noted 179 media fill vials lying on the shelf in the back room incubating all 14 days at 20-25 degrees -pharmacy has these temps documented-these represent the batch for the compounding pharmacist JB who is new to the role.*<br>*DH completed media fill 2-2-22 and 300 vials of 10ml and 8/13/21 simulating HD compounding, MH completed media fill for sterile non -HD 300 vials of 10ml, GH completed media fill simulating aqueous solutions 4/5/2022 (qty 155 vials 10ml representing non-HD Oct 8, 2021, MS completed media fill 4-22-22 and 10/15/21.* | Yes |
| 95. Documentation indicates compounding personnel have successfully completed didactic training, passed written competency assessments, undergone skill assessment using observational audit tools (hand hygiene, garbing, aseptic technique) and media-fill testing annually or semiannually (high risk) and before any compounding personnel begin to prepare CSPs . [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures]<br>*Documents of observational assessments for hand hygiene and garbing do not assess process for specific donning of coveralls to completely cover all exposed skin during lyophilization process.*<br>*Documentation of written and didactic assessments available from Critical Point.* | No |
| 96. Compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, are reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies. Corrective action is documented. Compounding personnel pass all evaluations prior to resuming compounding of sterile preparations. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] | Yes |
| 97. Other cleaning personnel performing cleaning and disinfecting procedures (e.g. environmental) are thoroughly trained in proper hand hygiene, and garbing, cleaning, and disinfection procedures by a qualified aseptic compounding expert. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] | N/A |
| 98. Compounding personnel and other personnel responsible for cleaning routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert. Visual observation of hand hygiene, garbing and cleaning is documented and maintained to provide a permanent record and long-term assessment of personnel competency. [ENVIRONMENTAL QUALITY AND CONTROL : Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] | Yes |
| 99. Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator collects a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates. The plates are incubated at 30-35° for 2–3 days. All compounding personnel have successfully completed an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling]<br>*Temps for MEA plates not properly documented for RPT MH-these indicate they are incubated at 30-33 degrees C on test date of 11-3-21. It is not documented the plates used for GFS have L&T.* | No |
| 100. Re-evaluation of glove fingertip testing onto appropriate agar plates (Trypticase soy agar (TSA) with lecithin and polysorbate 80) for all compounding personnel occurs at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs. Gloves shall not be disinfected with sterile 70% IPA prior to testing. The cfu action level is based on the total number of cfu on both gloves and not per hand. [ENVIRONMENTAL QUALITY AND CONTROL : Gloved Fingertip Sampling]<br>*See comments in #99.* | No |

**VERIFICATION**

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| 101. Labels of CSPs contain name and address of pharmacy, correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients]<br>*Labels do not contain Benzyl Benzoate preservative lot 04132022@15 on the label, also noted on Lipo C lot 03112022@16 Benzyl Alcohol not listed as a preservative.*<br>*Several vials such as Myers Cocktail do not contain the Federal Legend, specifically lot 04252022@5 or Magnesium Chloride/Taurine compound lot 03232022@19. These vials were noted to have black and white labels.* | No |
| 102. Facility has documentation that procedures have been followed to ensure sterility, purity, correct identities and amounts of ingredients, and stability. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures] | Yes |
| 103. CSP's are visually inspected for abnormal particulate matter and color, and intact containers and seals. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Inspection of Solution Dosage Forms and Review of Compounding Procedures] | Yes |
| 104. Beyond Use Dates are assigned using direct stability-indicating assays or authoritative literature that supports the assigned BUD. [STORAGE AND BEYOND-USE DATING : Determining Beyond-Use Dates] | Yes |

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| 105. Storage time of assembled bag and vial systems are according to the manufacturer recommendations. (eg Minibag plus, Addvantage, Add-ease) [STORAGE AND BEYOND-USE DATING : Proprietary Bag and Vial Systems] | N/A |

**DISPENSING/DISTRIBUTION**

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| 106. Facility has written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : ] | Yes |
| 107. Modes of transport are used that maintain appropriate temperatures and prevent damage to CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs] | Yes |
| 108. Facility provides a multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs. [PATIENT OR CAREGIVER TRAINING]<br>*Lyophilized peptides do not have any drug information provided to the patient.* | No |

**POLICY/PROCEDURE**

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| 109. Written procedures detail cleaning and disinfecting the sterile compounding areas including cleansers, disinfectants, and non-shedding wipe and mop materials. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas]<br>*Reviewed SOP 304.7* | Yes |
| 110. A written procedure is in place for cleaning and disinfecting the Direct Compounding Areas. [ENVIRONMENTAL QUALITY AND CONTROL : Cleaning and Disinfecting the Sterile Compounding Areas] | Yes |
| 111. Facility has written procedures to verify correct identity, quality, amounts, and purities of ingredients used in CSPs. [FINISHED PREPARATION RELEASE CHECKS AND TESTS : Identity and Strength Verification of Ingredients] | Yes |
| 112. Policies address packaging to maintain physical integrity, sterility, stability, and purity of CSPs. [MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs : Packaging and Transporting CSPs] | Yes |
| 113. Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding pharmacists to correct and prevent future problems. [PATIENT MONITORING AND ADVERSE EVENTS REPORTING]<br>*Documented on a QRE form* | Yes |

**RADIOPHARMACEUTICALS**

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| 114. Facility has appropriate primary engineering controls and radioactivity containment and shielding. Location of primary engineering controls permitted in ISO Class 8 controlled environment. [RADIOPHARMACEUTICALS AS CSPs] | |
| 115. Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD are prepared in a segregated compounding area. Segregated compounding area is designated with a line of demarcation. [RADIOPHARMACEUTICALS AS CSPs] | |
| 116. Technetium-99m/Molybdenum-99 generators are eluted in ISO Class 8 conditions. [RADIOPHARMACEUTICALS AS CSPs] | |

**MISCELLANEOUS**

| | |
|---|---|
| 117. Facility engaged in office use sterile compounding for human use is registered with FDA as an outsourcing facility. [FAC 64B16-27.700 (3)(g ]<br>*Pharmacy has Titan Medical (name of clinic) on top left of label vials of Hercules injection compound lot 02182022@21 stored at room temperature, vials were observed in the quarantine area-LG21820 Life File records demonstrate not dispensed. Batch record reviewed demonstrates 23 vials compounded.* | No |
| 118. Compounding records are properly maintained. [FAC 64B16-28.140(4)]<br>*Compounding records reviewed for Ipamorelin/Sermorelin PF 15mg/15mg Inj lot 01262022@15 shows hood as LFH1, however the drug was compounded in the BSC where the lyophilizer is attached, Bremlanotide PF 20mg Inj lot 03142022@15, batch record shows it was compounded in LFH1, however this drug was compounded in the BSC where the lyophilizer is attached. Documented theoretical yield is missing for Amino Acid #1 lot 04132022@15 -2250ml was the intended batch yield, actual yield was documented as 74 vials volume of 30ml,* | No |
| 119. When compounding activities require the manipulation of a patient's blood-derived or other biological material, the manipulations are clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they are controlled by specific standard operating procedures in order to avoid any cross-contamination. [ENVIRONMENTAL QUALITY AND CONTROL : Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas] | N/A |

**SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE**

| | |
|---|---|
| 120. Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.] | |
| 121. Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.] | |
| 122. Expired medications removed from the shelves. [64B16-28.110, F.A.C.] | |
| 123. CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.] | |
| 124. Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.] | |
| 125. Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.] | |
| 126. All controlled substance prescriptions contain information required. [893.04, F.S.] | |
| 127. Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date<br>meet the requirements of [456.42(2), F.S.]. | |
| 128. Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] | |
| 129. DEA 222 order forms properly completed. [893.07, F.S.] | |
| 130. Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.] | |
| 131. Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.] | |
| 132. Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.] | |
| 133. Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4), F.S.] | |
| 134. Pharmacy maintains invoices documenting that medicinal drugs were obtained from a Florida licensed distributor. 499.005 (14) | |

**LYOPHILIZATION**

# INV797-Sterile Compounding

Insp # 178092 | POPE SHENOUDA LLC | File # 22731

| | |
|---|---|
| 135. Sterile products prepared for lyophilization are maintained in ISO 5 unidirectional laminar flow air throughout sterilization, filling and transport to the lyophilizer. [64B16-27.797(5) F.A.C.] | Yes |
| 136. A recorded smoke study is available and demonstrates that transport from the PEC to the lyophilizer is accomplished in ISO 5 laminar flow air at all times. [64B16-27.797(5) F.A.C.]<br>*available for Feb 2022-performed by MTA* | Yes |
| 137.The pharmacy has established and follows policies and procedures for the high-level disinfection of the lyophilizer chamber, piping, and all other areas of the unit which pose a potential risk for contamination of the product. [64B16-27.797(5) F.A.C.]<br>*Contact time not adhered to based on study from Pharmetric* | No |
| 138. The pharmacy validated the high-level disinfection procedure initially, and after changes to the cleaning process or agents. Documentation of studies is available for inspection. [64B16-27.797(5) F.A.C.]<br>*Performed by Pharmetric on stainless steel; borosilicate glass (door) of the lyophilizer on Aug 17, 2020 : Cleaning agents documented are Peridox (contact time studied 10 mins), Decon-Phene 10 mins, SIPA 10 mins.* | Yes |
| 139. Validation studies for high level disinfection are performed with the 5-aerobic bacterial and fungal ATCC organisms referenced in USP<71> are conducted by an external vendor unless the firm has an internal laboratory capable of performing the studies. An internal laboratory is separate from the compounding and work areas of the pharmacy to prevent contamination in the pharmacy. [64B16-27.797(5) F.A.C.]<br>*Pharmetric conducted an evaluation on the stainless steel and borosilicate glass of the SP Scientific Lyophilizer SN SN 325488. attached to Esco HD vertical flow Class II A2 BSC on Aug 17, 2020* | Yes |
| 140. Policies and procedures are established and followed for cleaning the lyophilizer prior to disinfection and include cleaning agents and schedules. Documentation of cleaning is maintained and available for inspection. [64B16-27.797(5) F.A.C.]<br>*Procedures for use of Cleaning agents for the lyophilizer and dwell times used are not according the study done by Pharmetric lab on Aug 17, 2020 which documents a dwell time of 10 mins for Peridox and Decon Phene as well as SIPA. Infact only Hypo Chlor listed on cleaning log which has not been studied, Peridox and SIPA (no dwell times specified)*<br>*The pharmacy has a cleaning document "Daily Cleaning Log for Controlled Sterile Compounding Environments & Adjacent Areas" which has documented daily cleaning stating "Lyophilize (if no compound inside)", and reviewed "Maintenance and check the Lyophilizer" which has documented on production days March 2022 as "Weekly Inside the ISO 5" activity of cleaning Gaskets, Trays and shelves, Door and the handle", however this latter document only states "Wipe the lyo with SIPA" for outside the lyp.* | No |
| 141. Policies and procedures are established for the maintenance of the lyophilizer and at a minimum include the manufacturers recommendations. [64B16-27.797(5) F.A.C.]<br>*Pharmacy provided Intrutech Vacuum Gauge Calibration Certificate dated 10/6/21, Air Eze Scientific services did preventative maintenance for SP Scientific Freeze Dryer on 4-5-21.* | Yes |
| 142. The maintenance schedule includes provisions for periodic testing of the chamber for leaks and all other recommended procedures described by the equipment manufacturer. Documentation of routine maintenance is available for inspection. [64B16-27.797(5) F.A.C.]<br>*Testing for chamber leaks occurs monthly and is documented.* | Yes |
| 143.SOPs and quality assurance program established to include validation of the filling process, container closure integrity, frequent monitoring of fill volumes, identification of over fills and underfills, assessment of personnel involved in compounding for lyophilization, equipment qualification, formula verification, and evaluation of finished product for conformance to specifications. [64B16-27.797(5) F.A.C.] | Yes |
| 144. The pharmacy has provisions for sterilizing, with filters, the inert gas or air used for backfilling during the vacuum release phase. These Sterilizing filters undergo the manufacturers recommended integrity test. [64B16-27.797(5) F.A.C.]<br>*Documented on the batch record for lyophilized compounds.* | Yes |
| 145. Media fills are conducted every six months using the maximum batch size and demonstrate the filling, transport to the lyophilizer, loading and stoppering operations. Media is NOT frozen during the media fill operation. [64B16-27.797(5) F.A.C.]<br>*Media fills are approximately the representative batch size for compounded peptides.* | Yes |
| 146. Personnel preparing sterile compounds for lyophilization wear sterile Personal Protective Equipment that covers all exposed skin.[64B16-27.797(5) F.A.C.] | Yes |
| 147. Glove Fingertip Sampling is performed with every batch after fill and transport into the lyophilizer on all personnel compounding for lyophilization. The results are incorporated into the batch record. [64B16-27.797(5) F.A.C.]<br>*Documented on batch record for all Peptides, specifically noted to be TSA+ and MEA+ but does not specify L&T for compound Ipamorelin/Sermorelin PF 15mg/15mg Inj lot 01262022@15, compounding technician was DH. SOP 613 "Cleaning and maintenance of a SP Scientific Lyophilizer" does not specify the TSA plates for surface sampling.-see line 15. Observed correct TSA with L&T and MEA with L&T plates in refrigerator. Incubation temps are incorrect for MEA plates used-stated to be 30-33 degrees C.* | No |
| 148. In-process acceptance criteria such as color, moisture limits and visual appearance are established for each lyophilized product.[64B16-27.797(5) F.A.C.]<br>*Inspector identified vials of lyophilized compound which appear to be product ejection, specifically BPC-157 Acetate lot 01102022@16. This may impact product quality attributes. Other CSP's noted to have this visual defect: Semaglutide 5mg inj (not released).*<br>*In process criteria for rejection of different cake quality such as color, moisture, cake appearance not fully established to allow the inspector of the cake to reject or accept the end product.* | No |
| 149. A 100% visual examination of the finished product is conducted to determine that the product conforms to the established visual criteria and is incorporated into the batch record. [64B16-27.797(5) F.A.C.]<br>*See note above in #148- rejection criteria not established for some vials in this lot and has been released to patient.* | No |
| 150. Finished product testing is conducted on all batches. Procedures have been established for selecting test samples from the batch and are written and followed. Such procedures may include location of vials in the lyophilizer and positions in the fill line. [64B16-27.797(5) F.A.C.]<br>*On each batch record but not in SOP 613* | Yes |
| 151. Finished product testing includes sterility testing using a USP<71> method unless an alternative test method has been validated and shown to be equivalent or better. Diluents used to reconstitute the sample vials for testing are preservative free. [64B16-27.797(5) F.A.C.] | Yes |
| 152. Each batch of lyophilized product with a beyond use date that falls within the USP<797> guidelines and is not tested for sterility, has viable air and surface sampling that is collected in critical areas of ISO 5 locations as well as sampling of the gloves and sleeves of personnel documented in the batch record. [64B16-27.797(5) F.A.C.] | Yes |
| 153. Every lyophilized product has established endotoxin levels Each batch of lyophilized product is tested for endotoxin in accordance with USP<85> and confirmed to fall within the set limits and documented in the batch record. [64B16-27.797(5) F.A.C.] | Yes |
| 154. Potency, radiochemical purity or applicable test to assure label claim is conducted on every batch and documented in the batch record. In lieu of potency testing, weight based verification may occur based on formula verification. Potency testing shall be based on the USP monograph if one is available. [64B16-27.797(5) F.A.C.] | Yes |

**CORRECTIVE ACTION PLAN**

| | |
|---|---|
| 155. A corrective action plan is required to be submitted within 30 days for the non-compliant items listed above. | No |

## Remarks:

The retail pharmacy inventory is no longer at this location-medicinal drugs are missing and have been moved to Cross pharmacy. According to the PDM, the medicinal drugs were sold to MMG Pharma. The pharmacy compounds non-sterile and sterile compounds at this location.
Inspectors were informed, the pharmacy is not licensed in Texas or California but ships patient specific CSP to the physician clinic who then mails it to the patient. The pharmacy does document decontamination with cleaning agents after each batch.
Inspection conducted with Mina Shenouda, Pharmacy Intern and George Hanna, PDM and Joseph Bishay, pharmacist.
3 computer systems: PK for compounding, Life file (e-prescribed) and Prime Rx (retail which has been discontinued).

# INV797-Sterile Compounding

Insp # 178092

POPE SHENOUDA LLC

File # 22731

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Inspector Signature

CULLIPHER, MALA

Date:4/28/2022

Representative:

George Hanna

Date:4/28/2022

# 1st Choice Pharmacy

May 15th, 2022

Florida Department of Health
Division of Medical Quality Assurance
The Board of Pharmacy
4052 Bald Cypress Way, Bin #C-04
Tallahassee, FL 32399-3254

RE: State of Florida Department of Health Investigative Services INV797 – Sterile Compounding, File # 22731, Insp # 178902, Date 4/28/2022, Pharmacy Permit 20208

The State of Florida Department of Health Investigative Services, represented by Ms. Mala Cullipher, Completed an inspection on April 28th, 2022. Although no Corrective Action Plan or follow-up was requested by inspector, 1st Choice Compounding Pharmacy submits the following Corrective Actions for deficiencies that were listed on the INV797 – Sterile Compounding:

| Item # | Type | Inspection Item | Inspection Notes | Facility Response/Corrective Action/Comments |
|---|---|---|---|---|
| 45 | [HAZARDOUS DRUGS AS CSPs] | Hazardous drugs are prepared in an ISO Class 5 environment (BSC or CACI) with protective engineering controls in place, following aseptic practices specified for the appropriate contamination risk levels. | HD's such as Testosterone and Nandrolone compounded in the same BSC where Peptides such as Semaglutide, Sermorelin, Ipamorelin and CJC combinations are compounded. These HD's may pose a risk of contamination to the non-HD peptide where partially stoppered vials are lyophilized over several hours and then removed and crimped in the BSC. The pharmacy is decontaminating the BSC after each batch with Peridox. | The pharmacy, as noted by the inspector, is decontaminating the BSC after each batch using an approved operating procedure and the approved materials including Peridox RTU. Peridox RTU has been demonstrated to be an effective decontaminate when used as directed, thereby eliminating the cross-contamination risk between batches of drugs. |
| 62 | [ENVIRONMENTAL QUALITY AND CONTROL: Facility Design and Environmental Controls] | Surfaces and essential furniture in buffer rooms or zones and clean rooms are nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants. | Peridox applied in pass through of non-HD IV room did not remove stain or residue in the center of the pass-through, some screws still noted to be discolored and rusted on rivets/threshold in between the ante area and buffer room. The rusty nail was fixed during the inspection as well as threshold cleaner. There is a cart with | All discolored rivets and screws have been coated with an oxidizer and then coated with silicone. The cart legs have also been coated with oxidizer and sealed using enamel paint. All horizontal surfaces required for structural stability and safety meet all requirements of USP, including being non-porous, |

# 1st Choice Pharmacy

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| | | | slightly rusted legs visible and somewhat comes off when wiped off. Cleanroom has ledges in this modular unit-ledges are not recommended by USP. | smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants. As noted by inspector, recommendations are not requirements. |
| 78 | [ENVIRONMENTAL QUALITY AND CONTROL: Cleaning and Disinfecting the Sterile Compounding Areas] | Cleaning and disinfecting agents and methods of application are in accordance with written SOPs and followed by custodial and/or compounding personnel. | Daily cleaning log reviewed - demonstrates Hyp-chlor followed by Peridox RTU and SIPA, however documents show hypochlor is used, but none in cleanroom, Decon spore used. Each PEC is listed and Lyophilizer listed. Cleaning documentation - procedure does not match policy. | Policy & Procedure (SOP 304.8) has been updated to include only Sterile Water for irrigation, Peridox RTU as cleaning agents, and Sterile IPA as the disinfectant. |
| 85 | [ENVIRONMENTAL QUALITY AND CONTROL: Cleaning and Disinfecting the Sterile Compounding Areas] | Shelving, walls, and ceilings in ante-areas and buffer areas are cleaned and disinfected at least monthly. | For months of Feb, used Peridox and SIPA, however, only documented a disinfecting agent for monthly cleaning using Decon-Ahol and IPA | Please see response to #78 |
| 95 | [ENVIRONMENTAL QUALITY AND CONTROL: Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures] | Documentation indicates compounding personnel have successfully completed didactic training, passed written competency assessments, undergone skill assessment using observational audit tools (hand hygiene, garbing, aseptic technique) and media-fill testing annually or semiannually (high risk) and before any compounding personnel begin to prepare CSPs . | Documents of observational assessments for hand hygiene and garbing do not assess process for specific donning of coveralls to completely cover all exposed skin during lyophilization process. Documentation of written and didactic assessments available from Critical Point. | Policy & Procedure SOP F-410.a - Gowning and Gloving has been updated to include measures to minimize the potential to create external contamination when garbing using sterile hoods which cover all exposed skin when using sterile goggles. |

# 1st Choice Pharmacy

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| 99 | [ENVIRONMENTAL QUALITY AND CONTROL: Gloved Fingertip Sampling] | Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator collects a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates. The plates are incubated at 30-35° for 2–3 days. All compounding personnel have successfully completed an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use. | Temps for MEA plates not properly documented for RPT MH-these indicate they are incubated at 30-33 degrees C on test date of 11-3-21. It is not documented the plates used for GFS have L&T. | SOP F-202.b has been updated to reflect that all plates used for GFS contain lecithin and polysorbate 80 |
| 100 | [ENVIRONMENTAL QUALITY AND CONTROL: Gloved Fingertip Sampling] | Re-evaluation of glove fingertip testing onto appropriate agar plates (Trypticase soy agar (TSA) with lecithin and polysorbate 80) for all compounding personnel occurs at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs. Gloves shall not be disinfected with sterile 70% IPA prior to testing. The cfu action level is based on the total number of cfu on | See comments in #99. | Please see the reply for #99. |

# 1st Choice Pharmacy

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| | | both gloves and not per hand. | | |
| 101 | [FINISHED PREPARATION RELEASE CHECKS AND TESTS: Identity and Strength Verification of Ingredients] | Labels of CSPs contain name and address of pharmacy, correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration. | Labels do not contain Benzyl Benzoate preservative lot 04132022@15 on the label, also noted on Lipo C lot 03112022@16 Benzyl Alcohol not listed as a preservative. Several vials such as Myers Cocktail do not contain the Federal Legend, specifically lot 04252022@5 or Magnesium Chloride/Taurine compound lot 03232022@19. These vials were noted to have black and white labels. | All printed dispensing labels shall be updated to include preservative content, federal legend and shall be printed in color. |
| 108 | [PATIENT OR CAREGIVER TRAINING] | Facility provides a multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs. | Lyophilized peptides do not have any drug information provided to the patient | Package inserts have been updated for all peptides. |
| 117 | [FAC 64B16-27.700 (3)(g ] | Facility engaged in office use sterile compounding for human use is registered with FDA as an outsourcing facility. | Pharmacy has Titan Medical (name of clinic) on top left of label vials of Hercules injection compound lot 02182022@21 stored at room temperature; vials were observed in the quarantine area-LG21820 Life File records demonstrate not dispensed. Batch record reviewed demonstrates 23 vials compounded. | All vials quarantined for disposal have been disposed of. No vials dispensed. |
| 118 | [FAC 64B16-28.140(4)] | Compounding records are properly maintained. | Compounding records reviewed for Ipamorelin/Sermorelin PF 15mg/15mg Inj lot 01262022@15 shows hood as LFH1, however the drug was compounded in the BSC where | Compounding records have been updated to reflect the correct hood. Batch Amino Acid #1 Lot 04132022@15 batch yield of 74 vials (2220mL) was within the |

# 1st Choice Pharmacy

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| | | | the lyophilizer is attached, Bremlanotide PF 20mg Inj lot 03142022@15, batch record shows it was compounded in LFH1, however this drug was compounded in the BSC where the lyophilizer is attached. Documented theoretical yield is missing for Amino Acid #1 lot 04132022@15 -2250ml was the intended batch yield, actual yield was documented as 74 vials volume of 30ml, | tolerance to allow for fluid retention and/or cohesion in tubing, sterilizing filter and beaker. |
| 137 | [64B16-27.797(5) F.A.C.] | The pharmacy has established and follows policies and procedures for the high-level disinfection of the lyophilizer chamber, piping, and all other areas of the unit which pose a potential risk for contamination of the product. | Contact time not adhered to based on study from Pharmetric | SOP 613.1updated to correct contact time. |
| 140 | [64B16-27.797(5) F.A.C.] | Policies and procedures are established and followed for cleaning the lyophilizer prior to disinfection and include cleaning agents and schedules. Documentation of cleaning is maintained and available for inspection. | Procedures for use of Cleaning agents for the lyophilizer and dwell times used are not according the study done by Pharmetric lab on Aug 17, 2020 which documents a dwell time of 10 mins for Peridox and Decon Phene as well as SIPA. Infact only Hypo Chlor listed on cleaning log which has not been studied, Peridox and SIPA (no dwell times specified) The pharmacy has a cleaning document "Daily Cleaning Log for Controlled Sterile Compounding Environments & Adjacent Areas" which has documented daily cleaning stating "Lyophilize (if no compound inside)", and reviewed "Maintenance and check the Lyophilizer" which has documented on production days March 2022 as "Weekly Inside | Please see reply for #137. |

# 1st Choice Pharmacy

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| | | | the ISO 5" activity of cleaning Gaskets, Trays and shelves, Door and the handle", however this latter document only states "Wipe the lyo with SIPA" for outside the lyp. | |
| 147 | [64B16-27.797(5) F.A.C.] | Glove Fingertip Sampling is performed with every batch after fill and transport into the lyophilizer on all personnel compounding for lyophilization. The results are incorporated into the batch record. | Documented on batch record for all Peptides, specifically noted to be TSA+ and MEA+ but does not specify L&T for compound Ipamorelin/Sermorelin PF 15mg/15mg Inj lot 01262022@15, compounding technician was DH. SOP 613 "Cleaning and maintenance of a SP Scientific Lyophilizer" does not specify the TSA plates for surface sampling. -see line 15. Observed correct TSA with L&T and MEA with L&T plates in refrigerator. Incubation temps are incorrect for MEA plates used-stated to be 30-33 degrees C. | Please see reply for #99. |
| 148 | [64B16-27.797(5) F.A.C.] | In-process acceptance criteria such as color, moisture limits and visual appearance are established for each lyophilized product. | Inspector identified vials of lyophilized compound which appear to be product ejection, specifically BPC-157 Acetate lot 01102022@16. This may impact product quality attributes. Other CSP's noted to have this visual defect: Semaglutide 5mg inj (not released). In process criteria for rejection of different cake quality such as color, moisture, cake appearance not fully established to allow the inspector of the cake to reject or accept the end product | The lyophilized product labeled by the inspector "which appear to be product ejection" are, in fact, not product ejection but are actually just droplets from the fill process which splash and collect on the inner surface of the vial and sublimate. "Visual defects" in this case do NOT affect the product quality attributes based on potency testing and beyond use date testing. SOP 616.1 has been updated to establish criteria for rejection of different cake qualities. |
| 149 | [64B16-27.797(5) F.A.C.] | A 100% visual examination of the finished product is conducted to | See note above in #148-rejection criteria not established for some vials in this lot and has been released to patient. | Please see reply for #148. |

# 1st Choice Pharmacy

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|---|---|---|---|---|
| | | determine that the product conforms to the established visual criteria and is incorporated into the batch record. | | |

If there are any questions or to request additional information, please do not hesitate to contact me.

Respectfully,



George Hanna
Owner/Pharmacist in Charge
1st Choice Compounding Pharmacy

2228 US HWY 19 HOLIDAY, FLORIDA 34691
PHONE: (727) 934-1300 FAX: (727)-934-1313

1st CHOICE PHARMACY

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (04/22/2021)

**Section 1: Pharmacy/Wholesaler Information**

Name of Pharmacy/Wholesaler: Pope Shenouda LLC dba 1st Choice Pharmacy

Physical Address: 2228 US Hwy 19 N

City: Holiday State: FL Zip: 34691

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 727-934-1300 Website: 1stchoicepharmacy.net

Licensing Company Email: firstchoicepharmacy@yahoo.com

**Section 2: Personal Information**

First: Joseph Middle: Kyrillos Last: Bishay

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Brighton Lake Rd

City: Land O Lakes State: FL Zip: 34638

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

Date of Service: From: _____ to: _____

Military Occupation/Specialty:

Branch: ☐ Army/Reserves ☐ Navy/Reserves ☐ Airforce/Reserves ☐ Marine Corps/Reserves ☐ Coast Guard/Reserves ☐ National Guard

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✔ |



Applicant's initials: JB

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Florida A & M University | | 08/08-05/14 | |
| **Address** | **City** | **State** | **Zip** |
| 1601 S Martin Luther King Jr Blvd | Tallahassee | FL | 32307 |
| Diploma/Degree obtained, if any | | | |
| PharmD | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Gaither High School | | 08/04-05/08 | |
| **Address** | **City** | **State** | **Zip** |
| 16200 N Dale Mabry Hwy | Tampa | FL | 33618 |
| Diploma/Degree obtained, if any | | | |
| High School Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 10/20- Current | [redacted] Brighton Lake Rd | Land O Lakes | FL | 34638 |
| 11/18-09/20 | [redacted] Hallandale Loop Apt [redacted] | Land O Lakes | FL | 34638 |
| 09/16-11/18 | [redacted] Trevally Loop Apt [redacted] | Trinity | FL | 34655 |
| 04/15-04/16 | [redacted] Oyster Bayou Way | Clearwater | FL | 33759 |
| 09/13-04/15 | [redacted] Basuto Drive | Trinity | FL | 34655 |
| 01/11-05/13 | [redacted] Midyette rd | Tallahassee | FL | 32301 |
| 08/08-01/11 | [redacted] Castelview Ct Apt [redacted] | Tallahassee | FL | 32301 |
| 07/90-08/08 | [redacted] Dawnview Drive | Tampa | FL | 33624 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| 1st Choice Pharmacy | | | 01/22-Current | |
| **Business Address** | | **City** | **State** | **Zip** |
| 2228 US HWY 19 N | | Holiday | FL | 34691 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 727-304-6079 | Pharmacist in Charge | | Approx 2,500 to date | |
| **Description of Duties** | | | | |
| PIC, Oversee all day to day operations inside the pharmacy | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Fusion Pharmuceuticals | | | 10/19-12/21 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 28821 US HWY 19 N | | Clearwater | FL | 33761 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 201-240-8487 | Pharmacist in Charge | | 4,500 | |
| **Description of Duties** | | | | |
| PIC, Oversaw all day to day operations in the pharmacy | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| MP Pharmacy | | | 11/18-10/19 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 28813 US Hwy 19 N | | Clearwater | FL | 33761 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 201-240-8487 | Staff Pharmacist | | 2,000 | |
| **Description of Duties** | | | | |
| Managing Techs/Interns, Final verification | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Tampa Family Health Centers | | | 12/18-Current | |
| **Business Address** | | **City** | **State** | **Zip** |
| 302 W Fletcher Ave #2 | | Tampa | FL | 33612 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 813-397-5300 | PRN Pharmacist | | 500 | |
| **Description of Duties** | | | | |
| PRN Pharmacist | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Benzer Pharmacy/Tampa Specialty Pharmacy | | | 02/18-11/18 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 5908 Brekenridge Parkway | | Tampa | FL | 33610 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 813-644-7277 | PRN/Staff/PIC | | 1,500 | |
| **Description of Duties** | | | | |
| Final Verification, managing techs and interns | | | | |

Continue on next page if additional space is needed.

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✔ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| | | | | |
| Reason/Charge | | | | |
| | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| | | | | |
| Name of Business/Industry/Entity | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

Date

Applicant's initials JB

I, Joseph Bishay, **certify that as the designated representative for**

Pope Shenouda LLC dba 1st Choice Pharmacy,

**that I am qualified as follows and will comply with the following:**

1. I am at least 21 years of age;
3. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. I will serve in this representative capacity for only one pharmacy or wholesaler at a time

Joseph Bishay

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date

Applicant's initials JB

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joseph Bishay

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/07/2022

Date

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**Please have this section completed in the presence of a Notary Public.**

State of Florida, ss. County of Pasco

I, Jamie Kristofik, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

12-7-2022

**Date**

Subscribed and Sworn to before me this 7th day of Dec.

**Notary Public Signature**

**JAMIE KRISTOFIK**
**Notary Public**
**State of Florida**
**Comm# HH305030**
**Expires 8/24/2026**

(Seal)

**BISHAY, JOSEPH** // TRANSCRIPT

Print

| Course | Credits | Course Status | Date Completed | Lesson | Status | Score |
|---|---|---|---|---|---|---|
| (1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#15840020) | 1 | Completed | Jan 1, 2022 9:06 PM | The History of Compounding and USP Sterile Compounding Chapters Lesson | Completed | - |
| (1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#15840020) | 1 | Completed | Jan 1, 2022 9:06 PM | The History of Compounding and USP Sterile Compounding Chapters Post Test | Completed, Passed | 90% |
| (2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#15840021) | 2 | Completed | Jan 1, 2022 10:47 PM | Primary Engineering Controls: Function, Use, Testing and Certification Lesson | Completed | - |
| (2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#15840021) | 2 | Completed | Jan 1, 2022 10:47 PM | Primary Engineering Controls: Function, Use, Testing and Certification Post Test | Completed, Passed | 80% |

| | | | | | | |
|---|---|---|---|---|---|---|
| (2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#15840031) | 2 | Completed | Jan 1, 2022 11:11 PM | Secondary Engineering *Controls*: Function, Use, Testing and Certification Lesson | Completed | - |
| (2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#15840031) | 2 | Completed | Jan 1, 2022 11:11 PM | Secondary Engineering Controls: Function, Use, Testing and Certification Post Test | Completed, Passed | 90% |
| (3) Personnel Sampling Metrics - Personnel Competency Testing in Aseptic Manipulation (#15840019) | 1 | Completed | Jan 1, 2022 11:26 PM | Personnel Competency Testing in Aseptic Manipulation Lesson | Completed | - |
| (3) Personnel Sampling Metrics - Personnel Competency Testing in Aseptic Manipulation (#15840019) | 1 | Completed | Jan 1, 2022 11:26 PM | Personnel Competency Testing in Aseptic Manipulation Post Test | Completed, Passed | 90% |

| | | | | | | |
|---|---|---|---|---|---|---|
| (3) Personnel Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#15840017) | 2 | *Completed* | Jan 2, 2022 12:29 AM | Personnel Hand Hygiene, Garbing and *Gloved* Fingertip Sampling Lesson | *Completed* | - |
| (3) Personnel Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#15840017) | 2 | Completed | Jan 2, 2022 12:29 AM | Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Post Test | Completed, Passed | 83.32% |
| (4) Viable Facility Sampling Metrics - Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions (#15840028) | 1 | Completed | May 11, 2022 9:54 AM | Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions Lesson | Completed | - |
| (4) Viable Facility Sampling Metrics - Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions (#15840028) | 1 | Completed | May 11, 2022 9:54 AM | Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions Post Test | Completed, Passed | 80% |

| | | | | | | |
|---|---|---|---|---|---|---|
| (4) Viable Facility Sampling Metrics - Overview of Environmental Monitoring (#15840018) | 1 | Completed | Jan 2, 2022 12:39 AM | Overview of Environmental Monitoring Lesson | Completed | - |
| (4) Viable Facility Sampling Metrics - Overview of Environmental Monitoring (#15840018) | 1 | Completed | Jan 2, 2022 12:39 AM | Overview of Environmental Monitoring Post Test | Completed, Passed | 80% |
| (4) Viable Facility Sampling Metrics - Viable Air and Surface Sampling (#15840022) | 0.5 | Completed | Jan 2, 2022 12:50 AM | Viable Air and Surface Sampling Lesson | Completed, Passed | - |
| (4) Viable Facility Sampling Metrics - Viable Air and Surface Sampling (#15840022) | 0.5 | Completed | Jan 2, 2022 12:50 AM | Viable Air and Surface Sampling Post Test | Completed, Passed | 80% |
| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#15840026) | 1 | Completed | May 3, 2022 9:06 PM | Cleaning and Disinfection of Primary Engineering Controls Lesson | Completed | - |

| | | | | | | |
|---|---|---|---|---|---|---|
| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#15840026) | 1 | Completed | May 3, 2022 9:06 PM | Cleaning and Disinfection of Primary Engineering Controls Post Test | Completed, Passed | 90% |
| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) (#15840025) | 1 | Completed | May 3, 2022 9:31 PM | Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) Lesson | Completed | - |
| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) (#15840025) | 1 | Completed | May 3, 2022 9:31 PM | Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) Post Test | Completed, Passed | 80% |
| (5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#15840014) | 1 | Completed | May 3, 2022 9:47 PM | Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Lesson | Completed | - |

| | | | | | | |
|---|---|---|---|---|---|---|
| (5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#15840014) | 1 | Completed | May 3, 2022 9:47 PM | Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Post Test | Completed, Passed | 100% |
| (6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#15840016) | 1 | Completed | May 3, 2022 10:00 PM | Aseptic Technique and Conduct in Controlled Environments Lesson | Completed | - |
| (6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#15840016) | 1 | Completed | May 3, 2022 10:00 PM | Aseptic Technique and Conduct in Controlled Environments Post Test | Passed | 80% |
| (6) Aseptic Technique and Related Work Practices - Sterile Compounding Outside of SCAs and Cleanroom Suites (#15840024) | 1 | Completed | May 3, 2022 10:25 PM | Sterile Compounding Outside of SCAs and Cleanroom Suites Lesson | Completed | - |

| | | | | | | |
|---|---|---|---|---|---|---|
| (6) Aseptic Technique and Related Work Practices - Sterile Compounding Outside of SCAs and Cleanroom Suites (#15840024) | 1 | Completed | May 3, 2022 10:25 PM | Sterile Compounding Outside of SCAs and Cleanroom Suites Post Test | Passed | 90% |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#15840027) | 1 | Completed | May 3, 2022 10:42 PM | Hazardous Drug Introduction and Overview Lesson | Completed | - |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#15840027) | 1 | Completed | May 3, 2022 10:42 PM | Hazardous Drug Introduction and Overview Post Test | Completed, Passed | 86.66% |
| (8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Primary and Secondary Engineering Controls (#15840015) | 1 | Completed | May 3, 2022 11:02 PM | Hazardous Drug Primary and Secondary Engineering Controls Lesson | Completed | - |

| | | | | | | |
|---|---|---|---|---|---|---|
| (8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Primary and Secondary Engineering Controls (#15840015) | 1 | Completed | May 3, 2022 11:02 PM | Hazardous Drug Primary and Secondary Engineering Controls Post Test | Completed, Passed | 80% |
| (8) Requirements and Best Practices Hazardous Drug Compounding – Hazardous Personal Protective Equipment (#15840023) | 1 | Completed | May 4, 2022 7:27 AM | Hazardous Drug Use of Personal Protective Equipment Lesson | Completed | - |
| (8) Requirements and Best Practices Hazardous Drug Compounding – Hazardous Personal Protective Equipment (#15840023) | 1 | Completed | May 4, 2022 7:27 AM | Hazardous Drug Use of Personal Protective Equipment Post Test | Completed, Passed | 90% |

1st Choice Pharmacy is a Limited Liability Company (LLC) owned by Pope Shenouda, LLC.

This LLC has one sole 100% owner named George Hanna. His information is as follows:

George Hanna
2835 Moonbeam Way
Clearwater, FL 33759
DOB: 04/10/1981

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/13/2022)

### Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Pope Shenouda LLC DBA 1st Choice Pharmacy

Pharmacy/MDEG/Wholesaler License # (if applicable):

Physical Address: 2228 US HWY 19 N

City: Holiday State: FL Zip: 34691

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 727-934-1300 Website: www.1stchoicepharmacy.net

Licensing Company Email: firstchoicepharmacy@yahoo.com

### Section 2: Personal Information

First: George Middle: Last: Hanna

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Moonbeam Way

City: Clearwater State: FL Zip: 33759

Telephone: [redacted] Email: firstchoicepharmacy@yahoo.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| | | | |
|---|---|---|---|
| School Name: Florida A & M University | | | From - To (MM/YY – MM/YY): 2001 - 4/2005 |
| Address | City | State | Zip |
| Diploma/Degree obtained, if any: Pharm D | | | |
| School Name: St Pete College | | | From - To (MM/YY – MM/YY): 8/97 - 5/2001 |
| Address | City | State | Zip |
| Diploma/Degree obtained, if any: AA | | | |
| School Name: Pinellas High School | | | From - To (MM/YY – MM/YY): 11/95 - 5/97 |
| Address | City | State | Zip |
| Diploma/Degree obtained, if any: Diploma | | | |
| School Name | | | From - To (MM/YY – MM/YY) |
| Address | City | State | Zip |
| Diploma/Degree obtained, if any | | | |
| School Name | | | From - To (MM/YY – MM/YY |
| Address | City | State | Zip |
| Diploma/Degree obtained, if any | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| | [redacted] Moonbeam Way | Clearwater | FL | 33759 |
| | [redacted] Country Trails Dr | Safety Harbor | FL | 34695 |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Pope Shenouda LLC DBA 1st Choice Pharmacy | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| 2228 US HWY 19 N | | Holiday | FL | 34691 |
| **Phone** | **Title** | | | |
| 727-934-1300 | Owner/Pharmacist | | | |
| **Description of Duties** | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| A and E of Tampa Bay LLC DBA 1st Choice LTC Pharmacy | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| 2049 Welbilt Blvd | | Trinity | FL | 34655 |
| **Phone** | **Title** | | | |
| 727-940-3521 | Owner | | | |
| **Description of Duties** | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | | |
| | | | | |
| **Description of Duties** | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | | |
| | | | | |
| **Description of Duties** | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | | |
| | | | | |
| **Description of Duties** | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | X |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | X |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | X |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | X |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | X | |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | X | X |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | X | |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | X |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | X |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| | | | | |
| Reason/Charge | | | | |
| | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| | | | | |
| Name of Business/Industry/Entity | | | | |
| | | | | |

**Provide explanation below:**

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

George Hanna

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/22/2022

Date

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Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Pasco

I, Jamie Kristofik, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/22/2022

Date

Subscribed and Sworn to before me this 22 day of Dec.

Notary Public Signature

JAMIE KRISTOFIK
Notary Public
State of Florida
Comm# HH305030
Expires 8/24/2026

(Seal)

**HANNA, GEORGE** // TRANSCRIPT

Print

| Course | Credits | Course Status | Date Completed | Lesson | Status | Score |
|---|---|---|---|---|---|---|
| (1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#10142397) | 1 | Completed | Aug 7, 2020 12:33 PM | The History of Compounding and USP Sterile Compounding Chapters Lesson | Completed | - |
| (1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#10142397) | 1 | Completed | Aug 7, 2020 12:33 PM | The History of Compounding and USP Sterile Compounding Chapters Post Test | Completed, Passed | 80% |
| (1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#13398761) | 1 | Completed | Feb 24, 2022 2:29 PM | The History of Compounding and USP Sterile Compounding Chapters Lesson | Completed | - |
| (1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#13398761) | 1 | Completed | Feb 24, 2022 2:29 PM | The History of Compounding and USP Sterile Compounding Chapters Post Test | Completed, Passed | 90% |
| (1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#7903114) | 1 | Completed | Aug 8, 2019 12:11 PM | The History of Compounding and USP Sterile Compounding Chapters Lesson | Completed | - |

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| (1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#7903114) | 1 | Completed | Aug 8, 2019 12:11 PM | The History of Compounding and USP Sterile Compounding Chapters Post Test | Passed | 80% |
| (2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#10142398) | 2 | Completed | Aug 7, 2020 4:42 PM | Primary Engineering Controls: Function, Use, Testing and Certification Lesson | Completed | - |
| (2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#10142398) | 2 | Completed | Aug 7, 2020 4:42 PM | Primary Engineering Controls: Function, Use, Testing and Certification Post Test | Completed, Passed | 93.33% |
| (2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#13398762) | 2 | Completed | Feb 24, 2022 3:16 PM | Primary Engineering Controls: Function, Use, Testing and Certification Lesson | Completed | - |
| (2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#13398762) | 2 | Completed | Feb 24, 2022 3:16 PM | Primary Engineering Controls: Function, Use, Testing and Certification Post Test | Completed, Passed | 93.33% |

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| (2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#7903115) | 2 | Completed | Aug 8, 2019 2:10 PM | Primary Engineering Controls: Function, Use, Testing and Certification Lesson | Completed | - |
| (2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#7903115) | 2 | Completed | Aug 8, 2019 2:10 PM | Primary Engineering Controls: Function, Use, Testing and Certification Post Test | Passed | 80% |
| (2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#10142399) | 2 | Completed | Aug 16, 2020 3:20 PM | Secondary Engineering Controls: Function, Use, Testing and Certification Lesson | Completed | - |
| (2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#10142399) | 2 | Completed | Aug 16, 2020 3:20 PM | Secondary Engineering Controls: Function, Use, Testing and Certification Post Test | Completed, Passed | 90% |

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| (2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#13398763) | 2 | Completed | Feb 25, 2022 12:48 PM | Secondary Engineering Controls: Function, Use, Testing and Certification Lesson | Completed | - |
| (2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#13398763) | 2 | Completed | Feb 25, 2022 12:48 PM | Secondary Engineering Controls: Function, Use, Testing and Certification Post Test | Completed, Passed | 80% |
| (2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#7903116) | 2 | Completed | May 15, 2020 12:55 PM | Secondary Engineering Controls: Function, Use, Testing and Certification Lesson | Completed | - |
| (2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#7903116) | 2 | Completed | May 15, 2020 12:55 PM | Secondary Engineering Controls: Function, Use, Testing and Certification Post Test | Passed | 80% |
| (3) Personal Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#10142400) | 2 | Completed | Aug 16, 2020 10:34 PM | Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Lesson | Completed | - |

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| (3) Personal Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#10142400) | 2 | Completed | Aug 16, 2020 10:34 PM | Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Post Test | Completed, Passed | 83.32% |
| (3) Personal Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#7903117) | 2 | Completed | May 15, 2020 2:55 PM | Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Lesson | Completed | - |
| (3) Personal Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#7903117) | 2 | Completed | May 15, 2020 2:55 PM | Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Post Test | Completed, Passed | 83.32% |
| (3) Personnel Sampling Metrics - Personnel Aseptic Media Fill and Competency Evaluation (#7903118) | 1 | Completed | May 15, 2020 3:15 PM | Personnel Aseptic Media Fill and Competency Evaluation Lesson | Completed | - |
| (3) Personnel Sampling Metrics - Personnel Aseptic Media Fill and Competency Evaluation (#7903118) | 1 | Completed | May 15, 2020 3:15 PM | Personnel Aseptic Media Fill and Competency Evaluation Post Test | Completed, Passed | 80% |
| (3) Personnel Sampling Metrics - Personnel Competency Testing in Aseptic Manipulation (#10142401) | 1 | Completed | Aug 16, 2020 10:54 PM | Personnel Competency Testing in Aseptic Manipulation Lesson | Completed | - |
| (3) Personnel Sampling Metrics - Personnel Competency Testing in Aseptic Manipulation (#10142401) | 1 | Completed | Aug 16, 2020 10:54 PM | Personnel Competency Testing in Aseptic Manipulation Post Test | Completed, Passed | 100% |

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| (3) Personnel Sampling Metrics - Personnel Competency Testing in Aseptic Manipulation (#13398765) | 1 | Completed | Feb 25, 2022 1:02 PM | Personnel Competency Testing in Aseptic Manipulation Lesson | Completed | - |
| (3) Personnel Sampling Metrics - Personnel Competency Testing in Aseptic Manipulation (#13398765) | 1 | Completed | Feb 25, 2022 1:02 PM | Personnel Competency Testing in Aseptic Manipulation Post Test | Completed, Passed | 80% |
| (3) Personnel Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#13398764) | 2 | Completed | Feb 28, 2022 1:39 PM | Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Lesson | Completed | - |
| (3) Personnel Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#13398764) | 2 | Completed | Feb 28, 2022 1:39 PM | Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Post Test | Completed, Passed | 100% |
| (4) Viable Facility Sampling Metrics - Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions (#11362473) | 1 | Completed | Nov 20, 2020 11:40 AM | Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions Lesson | Completed, Passed | - |
| (4) Viable Facility Sampling Metrics - Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions (#11362473) | 1 | Completed | Nov 20, 2020 11:40 AM | Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions Post Test | Completed, Passed | 100% |

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| (4) Viable Facility Sampling Metrics - Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions (#11362497) | 1 | Completed | Mar 10, 2022 11:52 AM | Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions Lesson | Completed | - |
| (4) Viable Facility Sampling Metrics - Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions (#11362497) | 1 | Completed | Mar 10, 2022 11:52 AM | Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions Post Test | Completed, Passed | 90% |
| (4) Viable Facility Sampling Metrics - Overview of Environmental Monitoring (#10142406) | 1 | Completed | Aug 17, 2020 8:42 PM | Overview of Environmental Monitoring Lesson | Completed, Passed | - |
| (4) Viable Facility Sampling Metrics - Overview of Environmental Monitoring (#10142406) | 1 | Completed | Aug 17, 2020 8:42 PM | Overview of Environmental Monitoring Post Test | Completed, Passed | 80% |
| (4) Viable Facility Sampling Metrics - Overview of Environmental Monitoring (#13398770) | 1 | Completed | Feb 28, 2022 2:23 PM | Overview of Environmental Monitoring Lesson | Completed | - |
| (4) Viable Facility Sampling Metrics - Overview of Environmental Monitoring (#13398770) | 1 | Completed | Feb 28, 2022 2:23 PM | Overview of Environmental Monitoring Post Test | Completed, Passed | 80% |
| (4) Viable Facility Sampling Metrics - Surface Sampling (#7903123) | 1 | Completed | May 15, 2020 4:21 PM | Surface Sampling Lesson | Completed | - |

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| (4) Viable Facility Sampling Metrics - Surface Sampling (#7903123) | 1 | Completed | May 15, 2020 4:21 PM | Surface Sampling Post Test | Completed, Passed | 80% |
| (4) Viable Facility Sampling Metrics - Viable Air and Surface Sampling (#10142402) | 0.5 | Completed | Aug 17, 2020 9:05 PM | Viable Air and Surface Sampling Lesson | Completed, Passed | - |
| (4) Viable Facility Sampling Metrics - Viable Air and Surface Sampling (#10142402) | 0.5 | Completed | Aug 17, 2020 9:05 PM | Viable Air and Surface Sampling Post Test | Completed, Passed | 80% |
| (4) Viable Facility Sampling Metrics - Viable Air and Surface Sampling (#13398766) | 0.5 | Completed | Feb 28, 2022 2:45 PM | Viable Air and Surface Sampling Lesson | Completed, Passed | - |
| (4) Viable Facility Sampling Metrics - Viable Air and Surface Sampling (#13398766) | 0.5 | Completed | Feb 28, 2022 2:45 PM | Viable Air and Surface Sampling Post Test | Completed, Passed | 90% |
| (4) Viable Facility Sampling Metrics - Volumetric Air Sampling (#7903119) | 1 | Completed | May 28, 2020 9:26 PM | Volumetric Air Sampling Lesson | Completed | - |
| (4) Viable Facility Sampling Metrics - Volumetric Air Sampling (#7903119) | 1 | Completed | May 28, 2020 9:26 PM | Volumetric Air Sampling Post Test | Completed, Passed | 90% |
| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#10142408) | 1 | Completed | Aug 17, 2020 9:25 PM | Cleaning and Disinfection of Primary Engineering Controls Lesson | Completed | - |

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| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#10142408) | 1 | Completed | Aug 17, 2020 9:25 PM | Cleaning and Disinfection of Primary Engineering Controls Post Test | Completed, Passed | 80% |
| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#13398772) | 1 | Completed | Mar 1, 2022 1:20 PM | Cleaning and Disinfection of Primary Engineering Controls Lesson | Completed | - |
| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#13398772) | 1 | Completed | Mar 1, 2022 1:20 PM | Cleaning and Disinfection of Primary Engineering Controls Post Test | Completed, Passed | 100% |
| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#7903125) | 1 | Completed | May 28, 2020 9:58 PM | Cleaning and Disinfection of Primary Engineering Controls Lesson | Completed | - |
| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#7903125) | 1 | Completed | May 28, 2020 9:58 PM | Cleaning and Disinfection of Primary Engineering Controls Post Test | Completed, Passed | 80% |

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| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) (#10142409) | 1 | Completed | Aug 17, 2020 9:46 PM | Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) Lesson | Completed | - |
| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) (#10142409) | 1 | Completed | Aug 17, 2020 9:46 PM | Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) Post Test | Completed, Passed | 80% |
| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) (#13398773) | 1 | Completed | Mar 1, 2022 1:37 PM | Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) Lesson | Completed | - |

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| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) (#13398773) | 1 | Completed | Mar 1, 2022 1:37 PM | Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) Post Test | Completed, Passed | 100% |
| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls and Segregated Compounding Areas (#7903126) | 1 | Completed | May 29, 2020 9:44 AM | Cleaning and Disinfection of Secondary Engineering Controls and Segregated Compounding Areas Lesson | Completed | - |
| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls and Segregated Compounding Areas (#7903126) | 1 | Completed | May 29, 2020 9:44 AM | Cleaning and Disinfection of Secondary Engineering Controls and Segregated Compounding Areas Post Test | Completed, Passed | 80% |
| (5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#10142407) | 1 | Completed | Aug 17, 2020 11:14 PM | Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Lesson | Completed | - |

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| (5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#10142407) | 1 | Completed | Aug 17, 2020 11:14 PM | Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Post Test | Completed, Passed | 90% |
| (5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#13398771) | 1 | Completed | Mar 1, 2022 1:53 PM | Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Lesson | Completed | - |
| (5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#13398771) | 1 | Completed | Mar 1, 2022 1:53 PM | Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Post Test | Completed, Passed | 100% |
| (5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#7903124) | 1 | Completed | May 29, 2020 10:54 AM | Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Lesson | Completed | - |

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| (5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#7903124) | 1 | Completed | May 29, 2020 10:54 AM | Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Post Test | Completed, Passed | 80% |
| (6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#10142410) | 1 | Completed | Aug 18, 2020 12:00 AM | Aseptic Technique and Conduct in Controlled Environments Lesson | Completed | - |
| (6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#10142410) | 1 | Completed | Aug 18, 2020 12:00 AM | Aseptic Technique and Conduct in Controlled Environments Post Test | Passed | 100% |
| (6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#13398774) | 1 | Completed | Mar 1, 2022 2:22 PM | Aseptic Technique and Conduct in Controlled Environments Lesson | Completed | - |
| (6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#13398774) | 1 | Completed | Mar 1, 2022 2:22 PM | Aseptic Technique and Conduct in Controlled Environments Post Test | Passed | 80% |

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| (6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#7903127) | 1 | Completed | May 29, 2020 11:11 AM | Aseptic Technique and Conduct in Controlled Environments Lesson | Completed | - |
| (6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#7903127) | 1 | Completed | May 29, 2020 11:11 AM | Aseptic Technique and Conduct in Controlled Environments Post Test | Passed | 100% |
| (6) Aseptic Technique and Related Work Practices - Sterile Compounding on Patient Units (#7903128) | 1 | Completed | May 29, 2020 2:00 PM | Sterile Compounding on Patient Units Lesson | Completed | - |
| (6) Aseptic Technique and Related Work Practices - Sterile Compounding on Patient Units (#7903128) | 1 | Completed | May 29, 2020 2:00 PM | Sterile Compounding on Patient Units Post Test | Passed | 80% |
| (6) Aseptic Technique and Related Work Practices - Sterile Compounding Outside of SCAs and Cleanroom Suites (#10142411) | 1 | Completed | Aug 18, 2020 12:18 AM | Sterile Compounding Outside of SCAs and Cleanroom Suites Lesson | Completed | - |
| (6) Aseptic Technique and Related Work Practices - Sterile Compounding Outside of SCAs and Cleanroom Suites (#10142411) | 1 | Completed | Aug 18, 2020 12:18 AM | Sterile Compounding Outside of SCAs and Cleanroom Suites Post Test | Passed | 100% |

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| (6) Aseptic Technique and Related Work Practices - Sterile Compounding Outside of SCAs and Cleanroom Suites (#13398775) | 1 | Completed | Mar 3, 2022 2:56 PM | Sterile Compounding Outside of SCAs and Cleanroom Suites Lesson | Completed | - |
| (6) Aseptic Technique and Related Work Practices - Sterile Compounding Outside of SCAs and Cleanroom Suites (#13398775) | 1 | Completed | Mar 3, 2022 2:56 PM | Sterile Compounding Outside of SCAs and Cleanroom Suites Post Test | Passed | 90% |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#10142403) | 1 | Completed | Aug 17, 2020 10:14 PM | Hazardous Drug Introduction and Overview Lesson | Completed | - |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#10142403) | 1 | Completed | Aug 17, 2020 10:14 PM | Hazardous Drug Introduction and Overview Post Test | Completed, Passed | 100% |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#13398767) | 1 | Completed | Mar 3, 2022 3:40 PM | Hazardous Drug Introduction and Overview Lesson | Completed | - |

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| (8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#13398767) | 1 | Completed | Mar 3, 2022 3:40 PM | Hazardous Drug Introduction and Overview Post Test | Completed, Passed | 93.33% |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#7903120) | 1 | Completed | Jun 1, 2020 3:37 PM | Hazardous Drug Introduction and Overview Lesson | Completed | - |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#7903120) | 1 | Completed | Jun 1, 2020 3:37 PM | Hazardous Drug Introduction and Overview Post Test | Passed | 90% |
| (8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Primary and Secondary Engineering Controls (#10142405) | 1 | Completed | Aug 17, 2020 10:59 PM | Hazardous Drug Primary and Secondary Engineering Controls Lesson | Completed | - |
| (8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Primary and Secondary Engineering Controls (#10142405) | 1 | Completed | Aug 17, 2020 10:59 PM | Hazardous Drug Primary and Secondary Engineering Controls Post Test | Completed, Passed | 80% |

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| (8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Primary and Secondary Engineering Controls (#13398769) | 1 | Completed | Mar 3, 2022 4:14 PM | Hazardous Drug Primary and Secondary Engineering Controls Lesson | Completed | - |
| (8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Primary and Secondary Engineering Controls (#13398769) | 1 | Completed | Mar 3, 2022 4:14 PM | Hazardous Drug Primary and Secondary Engineering Controls Post Test | Completed, Passed | 90% |
| (8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Work Practice Strategies (#7903122) | 2 | Completed | Jun 3, 2020 1:25 PM | Hazardous Drug Work Practice Strategies Lesson | Completed | - |
| (8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Work Practice Strategies (#7903122) | 2 | Completed | Jun 3, 2020 1:25 PM | Hazardous Drug Work Practice Strategies Post Test | Passed | 80% |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training (#11362475) | 1 | Completed | Nov 20, 2020 12:13 PM | Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training Lesson | Completed | - |

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| (8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training (#11362475) | 1 | Completed | Nov 20, 2020 12:13 PM | Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training Post Test | Completed, Passed | 91.66% |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training (#11362499) | 1 | Completed | Mar 10, 2022 12:40 PM | Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training Lesson | Completed | - |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training (#11362499) | 1 | Completed | Mar 10, 2022 12:40 PM | Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training Post Test | Completed, Passed | 91.66% |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport (#11362474) | 1 | Completed | Nov 20, 2020 1:10 PM | Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport Lesson | Completed | - |

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| (8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport (#11362474) | 1 | Completed | Nov 20, 2020 1:10 PM | Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport Post Test | Completed, Passed | 80% |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport (#11362498) | 1 | Completed | Mar 10, 2022 1:08 PM | Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport Lesson | Completed | - |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport (#11362498) | 1 | Completed | Mar 10, 2022 1:08 PM | Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport Post Test | Completed, Passed | 100% |
| (8) Requirements and Best Practices Hazardous Drug Compounding – Engineering Controls and Personal Protective Equipment (#7903121) | 2 | Completed | Jun 3, 2020 2:46 PM | Engineering Controls and Personal Protective Equipment Lesson | Completed | - |

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| (8) Requirements and Best Practices Hazardous Drug Compounding – Engineering Controls and Personal Protective Equipment (#7903121) | 2 | Completed | Jun 3, 2020 2:46 PM | Engineering Controls and Personal Protective Equipment Post Test | Passed | 90% |
| (8) Requirements and Best Practices Hazardous Drug Compounding – Hazardous Personal Protective Equipment (#10142404) | 1 | Completed | Aug 17, 2020 10:36 PM | Hazardous Drug Use of Personal Protective Equipment Lesson | Completed | - |
| (8) Requirements and Best Practices Hazardous Drug Compounding – Hazardous Personal Protective Equipment (#10142404) | 1 | Completed | Aug 17, 2020 10:36 PM | Hazardous Drug Use of Personal Protective Equipment Post Test | Completed, Passed | 80% |
| (8) Requirements and Best Practices Hazardous Drug Compounding – Hazardous Personal Protective Equipment (#13398768) | 1 | Completed | Mar 10, 2022 10:08 AM | Hazardous Drug Use of Personal Protective Equipment Lesson | Completed | - |
| (8) Requirements and Best Practices Hazardous Drug Compounding – Hazardous Personal Protective Equipment (#13398768) | 1 | Completed | Mar 10, 2022 10:08 AM | Hazardous Drug Use of Personal Protective Equipment Post Test | Completed, Passed | 90% |

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| (8) Requirements and Best Practices Hazardous Drug Compounding – Hazardous Personal Protective Equipment (#16982472) | 1 | Completed | Jul 27, 2022 1:05 AM | Hazardous Drug Use of Personal Protective Equipment Lesson | Completed | - |
| (8) Requirements and Best Practices Hazardous Drug Compounding – Hazardous Personal Protective Equipment (#16982472) | 1 | Completed | Jul 27, 2022 1:05 AM | Hazardous Drug Use of Personal Protective Equipment Post Test | Completed, Passed | 80% |

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| (8) Requirements and Best Practices Hazardous Drug Compounding – Engineering Controls and Personal Protective Equipment (#7896620) | 2 | Completed | Aug 22, 2019 4:58 PM | Engineering Controls and Personal Protective Equipment Post Test | Passed | 90% |
| (8) Requirements and Best Practices Hazardous Drug Compounding – Hazardous Personal Protective Equipment (#10142389) | 1 | Completed | Nov 16, 2020 9:54 AM | Hazardous Drug Use of Personal Protective Equipment Lesson | Completed | - |
| (8) Requirements and Best Practices Hazardous Drug Compounding – Hazardous Personal Protective Equipment (#10142389) | 1 | Completed | Nov 16, 2020 9:54 AM | Hazardous Drug Use of Personal Protective Equipment Post Test | Completed, Passed | 100% |
| (8) Requirements and Best Practices Hazardous Drug Compounding – Hazardous Personal Protective Equipment (#13398753) | 1 | Completed | Jan 4, 2022 11:14 PM | Hazardous Drug Use of Personal Protective Equipment Lesson | Completed | - |
| (8) Requirements and Best Practices Hazardous Drug Compounding – Hazardous Personal Protective Equipment (#13398753) | 1 | Completed | Jan 4, 2022 11:14 PM | Hazardous Drug Use of Personal Protective Equipment Post Test | Completed, Passed | 90% |

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| (8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport (#11362492) | 1 | Completed | Jan 4, 2022 11:47 PM | Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport Post Test | Completed, Passed | 80% |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport (#16982547) | 1 | Completed | Jul 27, 2022 1:13 AM | Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport Lesson | Completed | - |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport (#16982547) | 1 | Completed | Jul 27, 2022 1:13 AM | Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport Post Test | Completed, Passed | 80% |
| (8) Requirements and Best Practices Hazardous Drug Compounding – Engineering Controls and Personal Protective Equipment (#7896620) | 2 | Completed | Aug 22, 2019 4:58 PM | Engineering Controls and Personal Protective Equipment Lesson | Completed | - |

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| (8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training (#16982548) | 1 | Completed | Jul 27, 2022 1:10 AM | Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training Post Test | Completed, Passed | 83.33% |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport (#11362468) | 1 | Completed | Nov 17, 2020 11:10 AM | Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport Lesson | Completed | - |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport (#11362468) | 1 | Completed | Nov 17, 2020 11:10 AM | Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport Post Test | Completed, Passed | 80% |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport (#11362492) | 1 | Completed | Jan 4, 2022 11:47 PM | Work Practice Strategies: Receiving, Storage, Compounding, Labeling, Packaging, and Transport Lesson | Completed | - |

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| (8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training (#11362469) | 1 | Completed | Nov 17, 2020 11:14 AM | Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training Post Test | Completed, Passed | 100% |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training (#11362493) | 1 | Completed | Jan 4, 2022 11:36 PM | Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training Lesson | Completed | - |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training (#11362493) | 1 | Completed | Jan 4, 2022 11:36 PM | Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training Post Test | Completed, Passed | 91.66% |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training (#16982548) | 1 | Completed | Jul 27, 2022 1:10 AM | Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training Lesson | Completed | - |

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| (8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Primary and Secondary Engineering Controls (#16982473) | 1 | Completed | Jul 27, 2022 1:03 AM | Hazardous Drug Primary and Secondary Engineering Controls Lesson | Completed | - |
| (8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Primary and Secondary Engineering Controls (#16982473) | 1 | Completed | Jul 27, 2022 1:03 AM | Hazardous Drug Primary and Secondary Engineering Controls Post Test | Completed, Passed | 80% |
| (8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Work Practice Strategies (#7896621) | 2 | Completed | Aug 22, 2019 3:08 PM | Hazardous Drug Work Practice Strategies Lesson | Completed | - |
| (8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Work Practice Strategies (#7896621) | 2 | Completed | Aug 22, 2019 3:08 PM | Hazardous Drug Work Practice Strategies Post Test | Passed | 85% |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training (#11362469) | 1 | Completed | Nov 17, 2020 11:14 AM | Work Practice Strategies: Decontamination of HD Spaces, Management of Spills, and Staff Training Lesson | Completed | - |

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| (8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Primary and Secondary Engineering Controls (#10142390) | 1 | Completed | Nov 16, 2020 10:05 AM | Hazardous Drug Primary and Secondary Engineering Controls Lesson | Completed | - |
| (8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Primary and Secondary Engineering Controls (#10142390) | 1 | Completed | Nov 16, 2020 10:05 AM | Hazardous Drug Primary and Secondary Engineering Controls Post Test | Completed, Passed | 80% |
| (8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Primary and Secondary Engineering Controls (#13398754) | 1 | Completed | Jan 4, 2022 11:03 PM | Hazardous Drug Primary and Secondary Engineering Controls Lesson | Completed | - |
| (8) Requirements and Best Practices for Hazardous Drug Compounding – Hazardous Drug Primary and Secondary Engineering Controls (#13398754) | 1 | Completed | Jan 4, 2022 11:03 PM | Hazardous Drug Primary and Secondary Engineering Controls Post Test | Completed, Passed | 80% |

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| (8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#13398752) | 1 | Completed | Jan 4, 2022 10:37 PM | Hazardous Drug Introduction and Overview Post Test | Completed, Passed | 80% |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#16982471) | 1 | Completed | Jul 27, 2022 12:59 AM | Hazardous Drug Introduction and Overview Lesson | Completed | - |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#16982471) | 1 | Completed | Jul 27, 2022 12:59 AM | Hazardous Drug Introduction and Overview Post Test | Completed, Passed | 86.66% |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#7896619) | 1 | Completed | Aug 22, 2019 1:31 PM | Hazardous Drug Introduction and Overview Lesson | Completed | - |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#7896619) | 1 | Completed | Aug 22, 2019 1:31 PM | Hazardous Drug Introduction and Overview Post Test | Passed | 90% |

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| (6) Aseptic Technique and Related Work Practices - Sterile Compounding Outside of SCAs and Cleanroom Suites (#16982479) | 1 | Completed | Jul 27, 2022 12:56 AM | Sterile Compounding Outside of SCAs and Cleanroom Suites Lesson | Completed | - |
| (6) Aseptic Technique and Related Work Practices - Sterile Compounding Outside of SCAs and Cleanroom Suites (#16982479) | 1 | Completed | Jul 27, 2022 12:56 AM | Sterile Compounding Outside of SCAs and Cleanroom Suites Post Test | Passed | 100% |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#10142388) | 1 | Completed | Nov 16, 2020 10:09 AM | Hazardous Drug Introduction and Overview Lesson | Completed | - |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#10142388) | 1 | Completed | Nov 16, 2020 10:09 AM | Hazardous Drug Introduction and Overview Post Test | Completed, Passed | 86.66% |
| (8) Requirements and Best Practices for Hazardous Drug Compounding - Hazardous Drug Introduction and Overview (#13398752) | 1 | Completed | Jan 4, 2022 10:37 PM | Hazardous Drug Introduction and Overview Lesson | Completed | - |

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| (6) Aseptic Technique and Related Work Practices - Sterile Compounding on Patient Units (#7896627) | 1 | Completed | Aug 21, 2019 3:44 PM | Sterile Compounding on Patient Units Lesson | Completed | - |
| (6) Aseptic Technique and Related Work Practices - Sterile Compounding on Patient Units (#7896627) | 1 | Completed | Aug 21, 2019 3:44 PM | Sterile Compounding on Patient Units Post Test | Passed | 90% |
| (6) Aseptic Technique and Related Work Practices - Sterile Compounding Outside of SCAs and Cleanroom Suites (#10142396) | 1 | Completed | Nov 16, 2020 4:14 PM | Sterile Compounding Outside of SCAs and Cleanroom Suites Lesson | Completed | - |
| (6) Aseptic Technique and Related Work Practices - Sterile Compounding Outside of SCAs and Cleanroom Suites (#10142396) | 1 | Completed | Nov 16, 2020 4:14 PM | Sterile Compounding Outside of SCAs and Cleanroom Suites Post Test | Passed | 100% |
| (6) Aseptic Technique and Related Work Practices - Sterile Compounding Outside of SCAs and Cleanroom Suites (#13398760) | 1 | Completed | Jan 4, 2022 10:27 PM | Sterile Compounding Outside of SCAs and Cleanroom Suites Lesson | Completed | - |
| (6) Aseptic Technique and Related Work Practices - Sterile Compounding Outside of SCAs and Cleanroom Suites (#13398760) | 1 | Completed | Jan 4, 2022 10:27 PM | Sterile Compounding Outside of SCAs and Cleanroom Suites Post Test | Passed | 90% |

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| (6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#13398759) | 1 | Completed | Jan 4, 2022 10:11 PM | Aseptic Technique and Conduct in Controlled Environments Post Test | Passed | 90% |
| (6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#16982478) | 1 | Completed | Jul 27, 2022 12:53 AM | Aseptic Technique and Conduct in Controlled Environments Lesson | Completed | - |
| (6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#16982478) | 1 | Completed | Jul 27, 2022 12:53 AM | Aseptic Technique and Conduct in Controlled Environments Post Test | Passed | 90% |
| (6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#7896626) | 1 | Completed | Aug 21, 2019 3:27 PM | Aseptic Technique and Conduct in Controlled Environments Lesson | Completed | - |
| (6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#7896626) | 1 | Completed | Aug 21, 2019 3:27 PM | Aseptic Technique and Conduct in Controlled Environments Post Test | Passed | 80.95% |

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| (5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#7896623) | 1 | Completed | Aug 21, 2019 3:07 PM | Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Lesson | Completed | - |
| (5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#7896623) | 1 | Completed | Aug 21, 2019 3:07 PM | Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Post Test | Passed | 90% |
| (6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#10142395) | 1 | Completed | Nov 16, 2020 4:19 PM | Aseptic Technique and Conduct in Controlled Environments Lesson | Completed | - |
| (6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#10142395) | 1 | Completed | Nov 16, 2020 4:19 PM | Aseptic Technique and Conduct in Controlled Environments Post Test | Passed | 100% |
| (6) Aseptic Technique and Related Work Practices - Aseptic Technique and Conduct in Controlled Environments (#13398759) | 1 | Completed | Jan 4, 2022 10:11 PM | Aseptic Technique and Conduct in Controlled Environments Lesson | Completed | - |

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| (5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#13398756) | 1 | Completed | Jan 4, 2022 9:52 PM | Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Lesson | Completed | - |
| (5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#13398756) | 1 | Completed | Jan 4, 2022 9:52 PM | Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Post Test | Completed, Passed | 100% |
| (5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#16982475) | 1 | Completed | Jul 27, 2022 12:51 AM | Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Lesson | Completed | - |
| (5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#16982475) | 1 | Completed | Jul 27, 2022 12:51 AM | Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Post Test | Completed, Passed | 80% |

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| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls and Segregated Compounding Areas (#7896625) | 1 | Completed | Aug 21, 2019 2:19 PM | Cleaning and Disinfection of Secondary Engineering Controls and Segregated Compounding Areas Lesson | Completed | - |
| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls and Segregated Compounding Areas (#7896625) | 1 | Completed | Aug 21, 2019 2:19 PM | Cleaning and Disinfection of Secondary Engineering Controls and Segregated Compounding Areas Post Test | Passed | 80% |
| (5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#10142392) | 1 | Completed | Nov 16, 2020 4:24 PM | Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Lesson | Completed | - |
| (5) Sanitization of Pharmacy Controlled Environments - Overview of Cleaning and Disinfection of Pharmacy Controlled Environments (#10142392) | 1 | Completed | Nov 16, 2020 4:24 PM | Overview of Cleaning and Disinfection of Pharmacy Controlled Environments Post Test | Completed, Passed | 100% |

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| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) (#13398758) | 1 | Completed | Jan 4, 2022 1:37 AM | Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) Post Test | Completed, Passed | 80% |
| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) (#16982477) | 1 | Completed | Jul 27, 2022 12:48 AM | Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) Lesson | Completed | - |
| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) (#16982477) | 1 | Completed | Jul 27, 2022 12:48 AM | Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) Post Test | Completed, Passed | 90% |

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| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) (#10142394) | 1 | Completed | Nov 16, 2020 4:27 PM | Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) Lesson | Completed | - |
| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) (#10142394) | 1 | Completed | Nov 16, 2020 4:27 PM | Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) Post Test | Completed, Passed | 90% |
| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) (#13398758) | 1 | Completed | Jan 4, 2022 1:37 AM | Cleaning and Disinfection of Secondary Engineering Controls (Cleanroom Suites and Segregated Compounding Areas) Lesson | Completed | - |

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| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#16982476) | 1 | Completed | Jul 27, 2022 12:46 AM | Cleaning and Disinfection of Primary Engineering Controls Lesson | Completed | - |
| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#16982476) | 1 | Completed | Jul 27, 2022 12:46 AM | Cleaning and Disinfection of Primary Engineering Controls Post Test | Completed, Passed | 80% |
| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#7896624) | 1 | Completed | Aug 8, 2019 3:23 PM | Cleaning and Disinfection of Primary Engineering Controls Lesson | Completed | - |
| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#7896624) | 1 | Completed | Aug 8, 2019 3:23 PM | Cleaning and Disinfection of Primary Engineering Controls Post Test | Passed | 100% |

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| (4) Viable Facility Sampling Metrics - Volumetric Air Sampling (#7896618) | 1 | Completed | Aug 8, 2019 2:58 PM | Volumetric Air Sampling Lesson | Completed | - |
| (4) Viable Facility Sampling Metrics - Volumetric Air Sampling (#7896618) | 1 | Completed | Aug 8, 2019 2:58 PM | Volumetric Air Sampling Post Test | Passed | 80% |
| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#10142393) | 1 | Completed | Nov 16, 2020 4:36 PM | Cleaning and Disinfection of Primary Engineering Controls Lesson | Completed | - |
| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#10142393) | 1 | Completed | Nov 16, 2020 4:36 PM | Cleaning and Disinfection of Primary Engineering Controls Post Test | Completed, Passed | 80% |
| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#13398757) | 1 | Completed | Jan 4, 2022 1:18 AM | Cleaning and Disinfection of Primary Engineering Controls Lesson | Completed | - |
| (5) Sanitization of Pharmacy Controlled Environments - Cleaning and Disinfection of Primary Engineering Controls (#13398757) | 1 | Completed | Jan 4, 2022 1:18 AM | Cleaning and Disinfection of Primary Engineering Controls Post Test | Completed, Passed | 90% |

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| (4) Viable Facility Sampling Metrics - Overview of Environmental Monitoring (#16982474) | 1 | Completed | Jul 27, 2022 12:41 AM | Overview of Environmental Monitoring Post Test | Completed, Passed | 90% |
| (4) Viable Facility Sampling Metrics - Surface Sampling (#7896622) | 1 | Completed | Aug 8, 2019 1:57 PM | Surface Sampling Lesson | Completed | - |
| (4) Viable Facility Sampling Metrics - Surface Sampling (#7896622) | 1 | Completed | Aug 8, 2019 1:57 PM | Surface Sampling Post Test | Passed | 90% |
| (4) Viable Facility Sampling Metrics - Viable Air and Surface Sampling (#10142387) | 0.5 | Completed | Nov 16, 2020 4:39 PM | Viable Air and Surface Sampling Lesson | Completed, Passed | - |
| (4) Viable Facility Sampling Metrics - Viable Air and Surface Sampling (#10142387) | 0.5 | Completed | Nov 16, 2020 4:39 PM | Viable Air and Surface Sampling Post Test | Completed, Passed | 80% |
| (4) Viable Facility Sampling Metrics - Viable Air and Surface Sampling (#13398751) | 0.5 | Completed | Jan 3, 2022 11:14 PM | Viable Air and Surface Sampling Lesson | Completed, Passed | - |
| (4) Viable Facility Sampling Metrics - Viable Air and Surface Sampling (#13398751) | 0.5 | Completed | Jan 3, 2022 11:14 PM | Viable Air and Surface Sampling Post Test | Completed, Passed | 90% |
| (4) Viable Facility Sampling Metrics - Viable Air and Surface Sampling (#16982470) | 0.5 | Completed | Jul 27, 2022 12:43 AM | Viable Air and Surface Sampling Lesson | Completed, Passed | - |
| (4) Viable Facility Sampling Metrics - Viable Air and Surface Sampling (#16982470) | 0.5 | Completed | Jul 27, 2022 12:43 AM | Viable Air and Surface Sampling Post Test | Completed, Passed | 80% |

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| (4) Viable Facility Sampling Metrics - Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions (#16982546) | 1 | Completed | Jul 27, 2022 1:07 AM | Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions Lesson | Completed | - |
| (4) Viable Facility Sampling Metrics - Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions (#16982546) | 1 | Completed | Jul 27, 2022 1:07 AM | Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions Post Test | Completed, Passed | 90% |
| (4) Viable Facility Sampling Metrics - Overview of Environmental Monitoring (#10142391) | 1 | Completed | Nov 16, 2020 4:43 PM | Overview of Environmental Monitoring Lesson | Completed, Passed | - |
| (4) Viable Facility Sampling Metrics - Overview of Environmental Monitoring (#10142391) | 1 | Completed | Nov 16, 2020 4:43 PM | Overview of Environmental Monitoring Post Test | Completed, Passed | 90% |
| (4) Viable Facility Sampling Metrics - Overview of Environmental Monitoring (#13398755) | 1 | Completed | Jan 3, 2022 11:05 PM | Overview of Environmental Monitoring Lesson | Completed | - |
| (4) Viable Facility Sampling Metrics - Overview of Environmental Monitoring (#13398755) | 1 | Completed | Jan 3, 2022 11:05 PM | Overview of Environmental Monitoring Post Test | Completed, Passed | 80% |
| (4) Viable Facility Sampling Metrics - Overview of Environmental Monitoring (#16982474) | 1 | Completed | Jul 27, 2022 12:41 AM | Overview of Environmental Monitoring Lesson | Completed | - |

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| (4) Viable Facility Sampling Metrics - Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions (#11362467) | 1 | Completed | Nov 20, 2020 4:13 PM | Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions Lesson | Completed, Passed | - |
| (4) Viable Facility Sampling Metrics - Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions (#11362467) | 1 | Completed | Nov 20, 2020 4:13 PM | Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions Post Test | Completed, Passed | 90% |
| (4) Viable Facility Sampling Metrics - Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions (#11362491) | 1 | Completed | Jan 4, 2022 11:22 PM | Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions Lesson | Completed | - |
| (4) Viable Facility Sampling Metrics - Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions (#11362491) | 1 | Completed | Jan 4, 2022 11:22 PM | Investigation and Remediation of Viable Environmental Monitoring and Personnel Sampling Excursions Post Test | Completed, Passed | 80% |

| | | | | | | |
|---|---|---|---|---|---|---|
| (3) Personnel Sampling Metrics - Personnel Competency Testing in Aseptic Manipulation (#16982469) | 1 | Completed | Jul 27, 2022 12:34 AM | Personnel Competency Testing in Aseptic Manipulation Lesson | Completed | - |
| (3) Personnel Sampling Metrics - Personnel Competency Testing in Aseptic Manipulation (#16982469) | 1 | Completed | Jul 27, 2022 12:34 AM | Personnel Competency Testing in Aseptic Manipulation Post Test | Completed, Passed | 90% |
| (3) Personnel Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#13398749) | 2 | Completed | Jan 3, 2022 10:54 PM | Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Lesson | Completed | - |
| (3) Personnel Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#13398749) | 2 | Completed | Jan 3, 2022 10:54 PM | Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Post Test | Completed, Passed | 83.32% |
| (3) Personnel Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#16982468) | 2 | Completed | Jul 27, 2022 12:38 AM | Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Lesson | Completed | - |
| (3) Personnel Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#16982468) | 2 | Completed | Jul 27, 2022 12:38 AM | Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Post Test | Completed, Passed | 83.32% |

| | | | | | | |
|---|---|---|---|---|---|---|
| (3) Personal Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#7896616) | 2 | Completed | Aug 8, 2019 12:53 PM | Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Post Test | Passed | 80% |
| (3) Personnel Sampling Metrics - Personnel Aseptic Media Fill and Competency Evaluation (#7896617) | 1 | Completed | Aug 8, 2019 1:42 PM | Personnel Aseptic Media Fill and Competency Evaluation Lesson | Completed | - |
| (3) Personnel Sampling Metrics - Personnel Aseptic Media Fill and Competency Evaluation (#7896617) | 1 | Completed | Aug 8, 2019 1:42 PM | Personnel Aseptic Media Fill and Competency Evaluation Post Test | Passed | 80% |
| (3) Personnel Sampling Metrics - Personnel Competency Testing in Aseptic Manipulation (#10142386) | 1 | Completed | Nov 16, 2020 4:44 PM | Personnel Competency Testing in Aseptic Manipulation Lesson | Completed | - |
| (3) Personnel Sampling Metrics - Personnel Competency Testing in Aseptic Manipulation (#10142386) | 1 | Completed | Nov 16, 2020 4:44 PM | Personnel Competency Testing in Aseptic Manipulation Post Test | Completed, Passed | 80% |
| (3) Personnel Sampling Metrics - Personnel Competency Testing in Aseptic Manipulation (#13398750) | 1 | Completed | Jan 3, 2022 9:51 PM | Personnel Competency Testing in Aseptic Manipulation Lesson | Completed | - |
| (3) Personnel Sampling Metrics - Personnel Competency Testing in Aseptic Manipulation (#13398750) | 1 | Completed | Jan 3, 2022 9:51 PM | Personnel Competency Testing in Aseptic Manipulation Post Test | Completed, Passed | 80% |

| | | | | | | |
|---|---|---|---|---|---|---|
| (2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#7896615) | 2 | Completed | Aug 7, 2019 1:18 PM | Secondary Engineering Controls: Function, Use, Testing and Certification Lesson | Completed | - |
| (2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#7896615) | 2 | Completed | Aug 7, 2019 1:18 PM | Secondary Engineering Controls: Function, Use, Testing and Certification Post Test | Passed | 86.66% |
| (3) Personal Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#10142385) | 2 | Completed | Nov 16, 2020 4:49 PM | Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Lesson | Completed | - |
| (3) Personal Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#10142385) | 2 | Completed | Nov 16, 2020 4:49 PM | Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Post Test | Completed, Passed | 83.32% |
| (3) Personal Sampling Metrics - Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling (#7896616) | 2 | Completed | Aug 8, 2019 12:53 PM | Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling Lesson | Completed | - |

| | | | | | | |
|---|---|---|---|---|---|---|
| (2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#13398748) | 2 | Completed | Jan 3, 2022 9:40 PM | Secondary Engineering Controls: Function, Use, Testing and Certification Lesson | Completed | - |
| (2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#13398748) | 2 | Completed | Jan 3, 2022 9:40 PM | Secondary Engineering Controls: Function, Use, Testing and Certification Post Test | Completed, Passed | 80% |
| (2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#16982467) | 2 | Completed | Jul 27, 2022 12:32 AM | Secondary Engineering Controls: Function, Use, Testing and Certification Lesson | Completed | - |
| (2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#16982467) | 2 | Completed | Jul 27, 2022 12:32 AM | Secondary Engineering Controls: Function, Use, Testing and Certification Post Test | Completed, Passed | 80% |

| | | | | | | |
|---|---|---|---|---|---|---|
| (2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#7896614) | 2 | Completed | Aug 7, 2019 11:56 AM | Primary Engineering Controls: Function, Use, Testing and Certification Lesson | Completed | - |
| (2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#7896614) | 2 | Completed | Aug 7, 2019 11:56 AM | Primary Engineering Controls: Function, Use, Testing and Certification Post Test | Passed | 80% |
| (2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#10142384) | 2 | Completed | Nov 17, 2020 11:09 AM | Secondary Engineering Controls: Function, Use, Testing and Certification Lesson | Completed | - |
| (2) Engineering Controls for Sterile Compounding - Secondary Engineering Controls: Function, Use, Testing and Certification (#10142384) | 2 | Completed | Nov 17, 2020 11:09 AM | Secondary Engineering Controls: Function, Use, Testing and Certification Post Test | Completed, Passed | 100% |

| | | | | | | |
|---|---|---|---|---|---|---|
| (2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#13398747) | 2 | Completed | Jan 3, 2022 9:31 PM | Primary Engineering Controls: Function, Use, Testing and Certification Lesson | Completed | - |
| (2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#13398747) | 2 | Completed | Jan 3, 2022 9:31 PM | Primary Engineering Controls: Function, Use, Testing and Certification Post Test | Completed, Passed | 86.66% |
| (2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#16982466) | 2 | Completed | Jul 27, 2022 12:28 AM | Primary Engineering Controls: Function, Use, Testing and Certification Lesson | Completed | - |
| (2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#16982466) | 2 | Completed | Jul 27, 2022 12:28 AM | Primary Engineering Controls: Function, Use, Testing and Certification Post Test | Completed, Passed | 100% |

| | | | | | | |
|---|---|---|---|---|---|---|
| (1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#16982465) | 1 | Completed | Jul 27, 2022 12:25 AM | The History of Compounding and USP Sterile Compounding Chapters Post Test | Completed, Passed | 80% |
| (1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#7896613) | 1 | Completed | Aug 7, 2019 8:41 AM | The History of Compounding and USP Sterile Compounding Chapters Lesson | Completed | - |
| (1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#7896613) | 1 | Completed | Aug 7, 2019 8:41 AM | The History of Compounding and USP Sterile Compounding Chapters Post Test | Passed | 90% |
| (2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#10142383) | 2 | Completed | Sep 3, 2020 2:44 PM | Primary Engineering Controls: Function, Use, Testing and Certification Lesson | Completed | - |
| (2) Engineering Controls for Sterile Compounding - Primary Engineering Controls: Function, Use, Testing and Certification (#10142383) | 2 | Completed | Sep 3, 2020 2:44 PM | Primary Engineering Controls: Function, Use, Testing and Certification Post Test | Completed, Passed | 93.33% |

**SHENOUDA, MINA** // TRANSCRIPT

Print

| Course | Credits | Course Status | Date Completed | Lesson | Status | Score |
|---|---|---|---|---|---|---|
| (1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#10142382) | 1 | Completed | Sep 3, 2020 2:20 PM | The History of Compounding and USP Sterile Compounding Chapters Lesson | Completed | - |
| (1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#10142382) | 1 | Completed | Sep 3, 2020 2:20 PM | The History of Compounding and USP Sterile Compounding Chapters Post Test | Completed, Passed | 90% |
| (1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#13398746) | 1 | Completed | Jan 3, 2022 9:17 PM | The History of Compounding and USP Sterile Compounding Chapters Lesson | Completed | - |
| (1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#13398746) | 1 | Completed | Jan 3, 2022 9:17 PM | The History of Compounding and USP Sterile Compounding Chapters Post Test | Completed, Passed | 90% |
| (1) Fundamentals of Sterile Compounding - The History of Compounding and USP Sterile Compounding Chapters (#16982465) | 1 | Completed | Jul 27, 2022 12:25 AM | The History of Compounding and USP Sterile Compounding Chapters Lesson | Completed | - |

# *State of Florida*
# *Department of State*

I certify from the records of this office that POPE SHENOUDA LLC is a limited liability company organized under the laws of the State of Florida, filed on December 10, 2007, effective December 7, 2007.

The document number of this limited liability company is L07000122168.

I further certify that said limited liability company has paid all fees due this office through December 31, 2022, that its most recent annual report was filed on April 25, 2022, and that its status is active.

***Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twenty-seventh day of May, 2022***




***Secretary of State***

**Tracking Number: 9527925942CU**

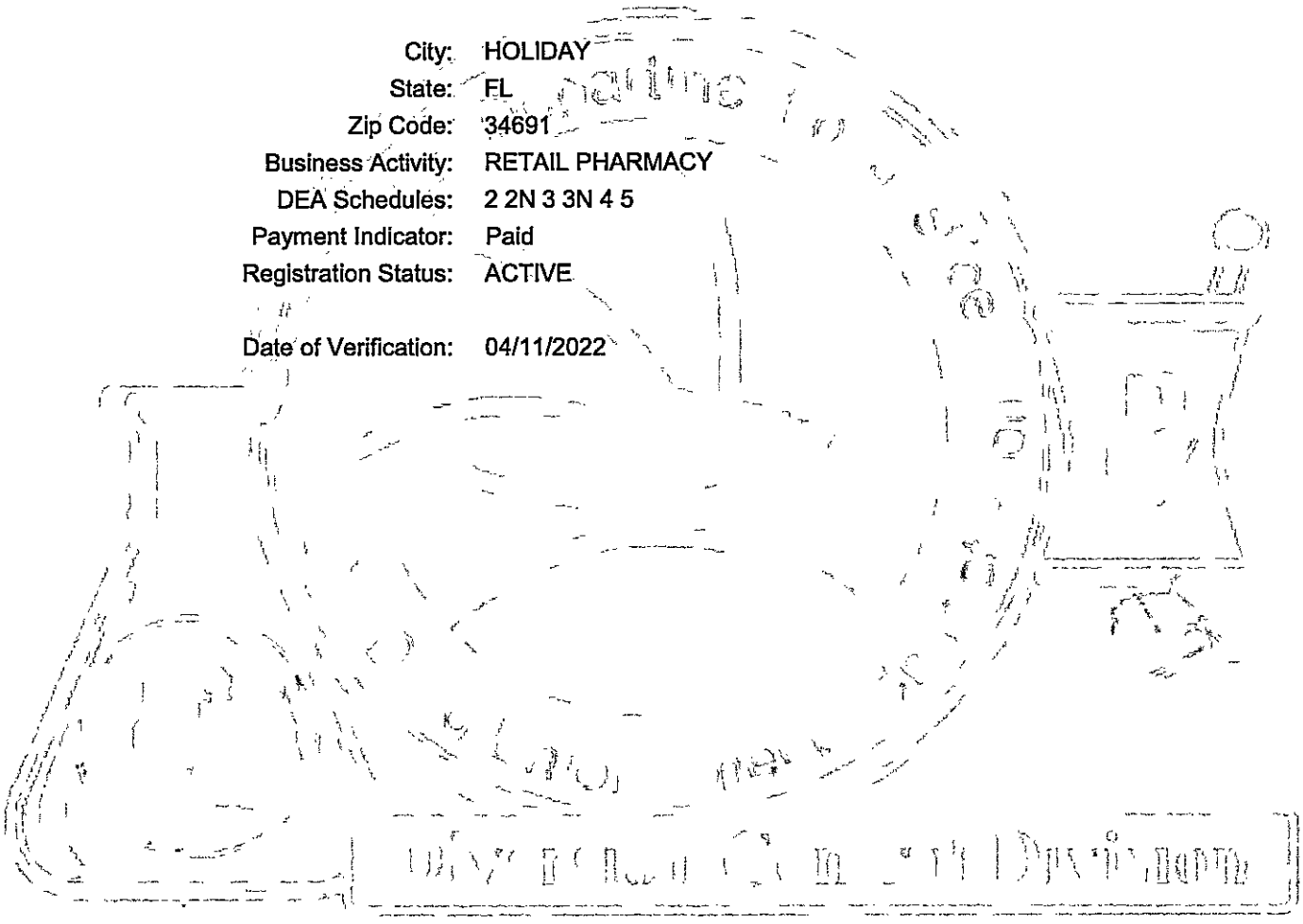
**To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.**

**https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication**

# Registrant Verification For

## POPE SHENOUDA, LLC

| | |
|---|---|
| DEA Number: | FP0721123 |
| Expiration Date: | 03/31/2023 |
| Additional Company Info: | 1ST CHOICE PHARMACY |
| Registered Address: | 2228 US HIGHWAY 19 |
| City: | HOLIDAY |
| State: | FL |
| Zip Code: | 34691 |
| Business Activity: | RETAIL PHARMACY |
| DEA Schedules: | 2 2N 3 3N 4 5 |
| Payment Indicator: | Paid |
| Registration Status: | ACTIVE |
| Date of Verification: | 04/11/2022 |



This Primary Source Verification was obtained from the Drug Enforcement Administration's Controlled Substance Act Registrant Database.

Drug Enforcement Administration • Diversion Control Division • 75 Morrissette Dr, Springfield, VA 22152

# Department of Health

## License Number: PH23208

*Data As Of 11/12/2022*

| | |
|---|---|
| **Profession** | Pharmacy |
| **License** | PH23208 |
| **License Status** | CLEAR/ |
| **Qualifications** | Community PharmacySchedule II & III |
| **License Expiration Date** | 2/28/2025 |
| **License Original Issue Date** | 02/20/2008 |
| **Address of Record** | 2228 US Hwy 19<br>HOLIDAY, FL 34691 |
| **Discipline on File** | No |
| **Public Complaint** | No |

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

# 9

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Pharmacy Application
## Non-Refundable $500.00 Fee

Rev (8/02/2022)

| Facility Location | Application Type (check all applicable) | Pharmacy Type (check all applicable) | Services the Pharmacy will Provide (check all applicable) |
|---|---|---|---|
| ☐ Nevada | ☒ New Pharmacy | ☒ Retail/Community | ☒ Retail/Community |
| ☒ Out-of-State | ☐ Ownership Change* | ☐ Hospital (# beds _____) | ☐ Non-sterile Compounding |
| | ☐ Location Change * | ☐ Internet | ☐ Sterile Compounding |
| | ☐ Name Change* | ☐ Nuclear | ☒ Mail-Order Service |
| | | ☐ Other: | ☐ Off-site Cognitive Services |
| | * If making a change, provide license #: | | ☐ Long Term Care |
| | | | ☐ Hospital |
| | PH_____ | | ☐ Other: |

| Days of Operation | | Ownership Type (check applicable box) |
|---|---|---|
| ☒ Monday | ☒ Friday | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12) |
| ☒ Tuesday | ☐ Saturday | ☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12) |
| ☒ Wednesday | ☐ Sunday | ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12) |
| ☒ Thursday | ☐ Holidays | ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12) |

## Section 1: General Information

Pharmacy Name: Seven Hills Pharmacy, LLC

Physical Address: 2722 E. Kemper Rd

City: Sharonville State: OH Zip: 45241

Mailing Address (if different from physical address): same

City: _____ State: _____ Zip: _____

Telephone: 513-771-0367 Toll Free # (NAC 639.708, NRS 639.23286): 844-643-0169

Fax: 513-771-0369 Contact Email: compliance@truepill.com

Website: N/A

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Christopher Spitzer ✓

Supervising/Managing Pharmacist NV Pharmacist Registration #: 21780 ✓

**Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)**

| | |
|---|---|
| Name: Christopher Spitzer | NV Pharmacist Registration #: 21780 |
| Name: Christopher Gibson | NV Pharmacist Registration #: 22645 |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |
| Name: | NV Pharmacist Registration #: |

| Section 3: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✔ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction? | | ✔ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry? | ✔ | |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✔ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✔ |

**If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.**

**Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)**

| | | |
|---|---|---|
| Name: N/A | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |
| Name: | Credentials: | %: |

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

**Section 5: Publicly Traded Corporation**

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

**Section 6: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: DE

Parent Company (if any): Postmeds, Inc.

Corporation/Organization Name: Seven Hills Pharmacy LLC

Mailing Address: 2722 E. Kemper Rd

City: Sharonville State: OH Zip: 45241

Telephone: 650-353-5495 Email: compliance@truepill.com

Contact Person Name: Loan Nguyen

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

**Section 7: Partnership**

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☒ No

**Section 8: Sole Owner**

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

**Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)**

## Statement of Responsibility

1. I am the Manager (title) for Seven Hills Pharmacy, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Daniel Simkin

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

12/9/22

Date

**Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding**

## Affidavit for Pharmacy License

I, Daniel Simkin hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Manager (title) for Seven Hills Pharmacy, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 9th day of December, 20 22

Notary Public

KEITH McGRUDER
COMM# 2293123
Notary Public - California
Los Angeles County
My comm. Expires July 12, 2023

| Section 12: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)** | ✓ | ✓ | | |
| • **List the top four stockholders and their percent ownership. NRS 639.231(3)** | ✓ | ✓ | | |
| • **List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)** | | ✓ | | |
| • **For General Partnerships, list the name of each partner. NAC 639.214(2)**<br>• **For Limited Partnerships, list the names of (NAC 639.214(3)):**<br>o **All General Partners;**<br>o **All Limited Partners who hold 10% or more of the interest.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** from the Secretary of State's Office where the business is domiciled, dated within the last **6 months.** | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative Form** http://bop.nv.gov/Services/newapps/Business/ must be completed by the Designated Representative. NAC 639.5005. The requirement does not apply to:<br>a. An applicant or a licensee that is a publicly traded corporation;<br>b. An applicant or licensee whose pharmacy is determined by the Board to be located within a large retail store, including, without limitation, a grocery store, variety store or department store under common ownership; or<br>c. An applicant or licenses in which a majority interest of the applicant or licensee is owned by a pharmacist who is:<br>1) License by the Board; and<br>2) A resident of this state. | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** http://bop.nv.gov/Services/newapps/Business/ must be completed by:<br>a. **For Non-publicly traded -** The top 4 shareholder/stockholders.<br>b. **For Partnerships -** All general partners; all limited partners who hold 10% or more of the interest.<br>c. **For Sole Owner** - The owner. | | ✓ | ✓ | ✓ |
| • **Sterile Compounding Questionnaire** must be completed if the pharmacy will provide sterile compounded drugs. Access form at http://bop.nv.gov/Services/newapps/Business/. | ✓ | ✓ | ✓ | ✓ |
| • **Submit a copy of your most recent pharmacy inspection** from the regulatory or licensing authority of the state, territory or Federal agency in which the pharmacy is located. **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2328(2)(f) | ✓ | ✓ | ✓ | ✓ |
| • **Submit a copy of your license, certification, permit or registration issued to your pharmacy** from the regulatory board or licensing authority of the state or territory in which the pharmacy is located. **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2328(2)(a) | ✓ | ✓ | ✓ | ✓ |
| • **License Verification** by the regulatory board or licensing authority of the state or territory in which the pharmacy is located. You may use the License Verification form here: http://bop.nv.gov/Services/newapps/Business/. **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2238(2)(g) | ✓ | ✓ | ✓ | ✓ |
| • **Copy of DEA Registration if handling controlled substances (REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** | ✓ | ✓ | ✓ | ✓ |
| • **Internet Pharmacy Services Certification (REQUIRED FOR PHARMACIES PROVIDING INTERNET PHARMACY SERVICES)** | ✓ | ✓ | ✓ | ✓ |
| • **Transmit Controlled Substance Prescription Data-** Pharmacies dispensing scheduled II-V controlled substance for human consumption shall, not later than the end of the next business day after dispensing a controlled substance, upload to the Nevada Prescription Monitoring Program (PMP) the information described in paragraph (d) of subsection 1 of NRS 453.162. Registration information found at: https://bop.nv.gov/links/PMP/ | ✓ | ✓ | ✓ | ✓ |

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Daniel Simkin

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

12/9/22
Date

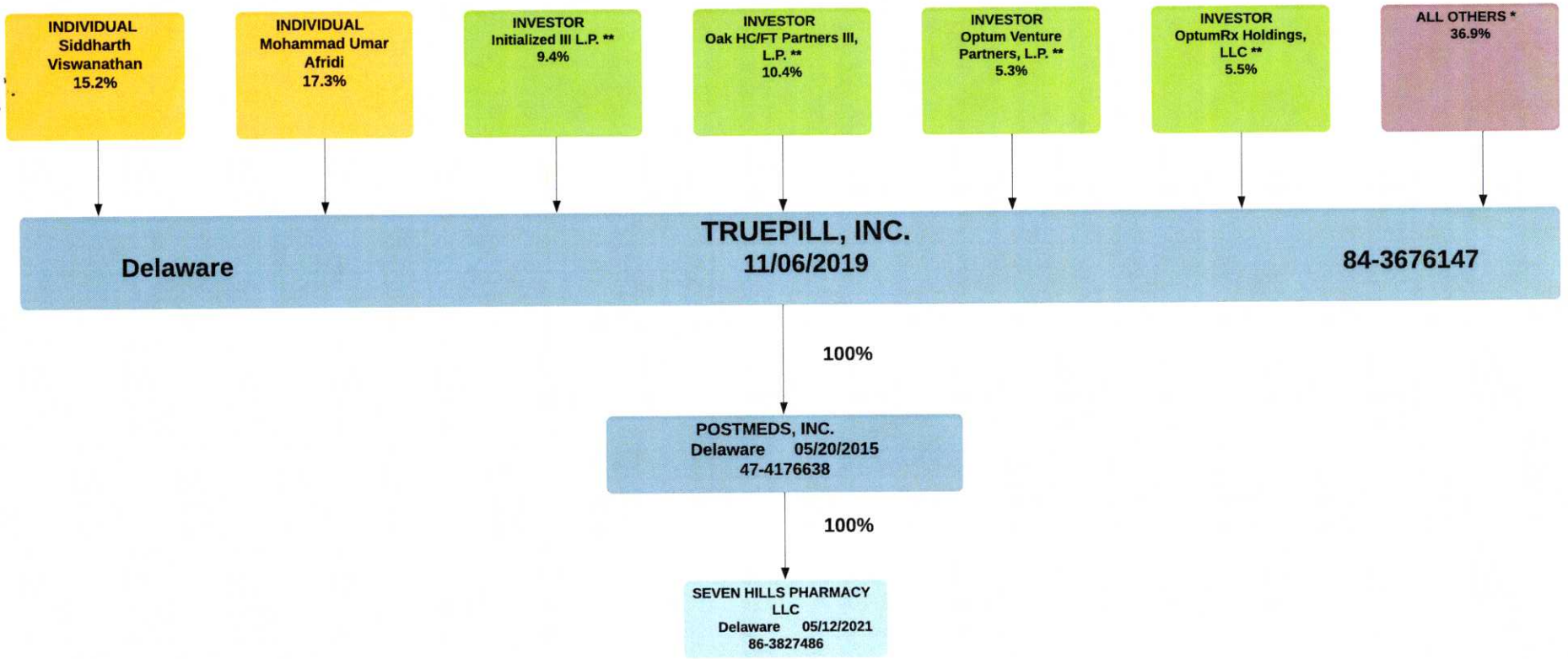
| Board Use Only | Date Received: 1·4·23 | Amount: 500 cc |
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1/25/23

Nov 3, 2021 10:06 AM

Seven Hills Pharmacy - Board of Pharmacy ONLY

**CONFIDENTIAL! DO NOT DISTRIBUTE TO THIRD PARTIES**




*No individual/entity in this group owns > = 3% of Truepill, Inc., and therefore no individul/entity in this group owns > = 5% of the Provider

**No individual owns >= 5% of Truepill, Inc., and therefore no individual/entity in this group owns > = 5% of the Provider

Corporation | Limited Liability Company | Investor | Individual | Other

This organizational chart was prepared by the Legal Team & contains entity name, state of domicile, date of formation & EIN.
For additional details, please contact entities@truepill.com

**List of Managers**

| Name | Title | Business Address | Home Address | Business Phone | Home Phone | SSN | DOB |
|---|---|---|---|---|---|---|---|
| Daniel Simkin | Manager | 3121 Diablo Ave, Hayward, CA 94545 | [redacted] Hyperion Ave, Los Angeles, CA 90029 | 650-353-5495 | [redacted] | [redacted] | [redacted] |
| Siddharth Viswanathan | Manager | 3121 Diablo Ave, Hayward, CA 94545 | [redacted] Long Bridge Street, Apt 514, San Francisco, CA 94158 | 650-353-5495 | | | |
| Mathew Davis-Ratner | Manager | 3121 Diablo Ave, Hayward, CA 94545 | [redacted] 51st Ave S, Seattle, WA 98118 | 650-353-5495 | | | |

# UNITED STATES OF AMERICA
# STATE OF OHIO
# OFFICE OF THE SECRETARY OF STATE

*I, Frank LaRose, do hereby certify that I am the duly elected, qualified and present acting Secretary of State for the State of Ohio, and as such have custody of the records of Ohio and Foreign business entities; that said records show SEVEN HILLS PHARMACY LLC, a Delaware Limited Liability Company, Registration Number 4684707, was registered in the State of Ohio on May 24, 2021, is currently authorized to transact business in this state.*

*Witness my hand and the seal of the Secretary of State at Columbus, Ohio this 11th day of October, A.D. 2022.*

**Ohio Secretary of State**

**Validation Number: 202228404922**

**State of Ohio Board of Pharmacy**

77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836 | http://www.pharmacy.ohio.gov

# License 0232000312

## Seven Hills Pharmacy Llc

2722 E Kemper Rd
Sharonville, OH 45241-1818
Hamilton County

## Terminal - Pharmacy - Category 3

## Outpatient Pharmacy Inspection

## November 7, 2022

# License 0232000312 - Seven Hills Pharmacy Llc

Full

**State of Ohio Board of Pharmacy**
77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836
http://www.pharmacy.ohio.gov

**Completed by** Sharon Shields
**Start** 11/7/2022 9:06 AM
**End** 11/7/2022 11:48 AM

## Organization

**Name**
Seven Hills Pharmacy Llc

**License Type**
Terminal - Pharmacy - Category 3

**Category**

**License Number**
0232000312

**Business Type**
II - Independent Community Retail (1 Outlet)

**DEA Number**

**Responsible Person**
Christopher Spitzer, R.Ph.

**Hours of Operation**
M-F 9a-5p; Sat/Sun closed

## Contact

**Address**
2722 E Kemper Rd
Sharonville, OH 45241-1818
Hamilton County

**Primary Number**
(727) 421-8504

**Fax Number**
(513) 771-0369

**Website**

## Personnel

| Name | Initials | Position | I.D. No. | Phone | Email |
|---|---|---|---|---|---|
| Christpoher Gibson, R.Ph. | | Pharmacist | 03236967 | | |
| Lisa Beth Klein | | Certified Pharmacy Technician | 09305487 | (414) 336-9652 | lklein15@gmail.com |
| Christopher Spitzer, R.Ph. | | Responsible Person | 03236754 | | |

### 1) Initial Inspection Information

**3) What is the name and current version of the dispensing software being used by the pharmacy?**

Observation
Pharmacy uses both Pioneer and TruePill operating system. Operating systems are client specific in their use. Pharmacy is phasing out use of Pioneer.

**5) Facility description**

Observation
Facility is a retail pharmacy servicing the patients of various online prescriber entities. Pharmacy has the ability to serve the community (walk-in patient). Pharmacy does not accept insurance. Pharmacy has limited drug stock. Pharmacy processes approximately 150 prescriptions per day. Pharmacy employs two pharmacists and one certified pharmacy technician. Pharmacy ships prescriptions to patients in Ohio and in other states using USPS, UPS, and FedEx.

### 2) * Licensing, Responsible Person and DEA Registration

**1) Have there been any changes in the facility's ownership, business name or trade name, category, or address without submitting a new application to the Board?**

No

**2) Does the responsible person match what is indicated in eLicense?**

Yes

**3) Does the pharmacy have a valid registration issued by the Drug Enforcement Administration?**

Yes

Observation
FS1293884 expires 2/28/2025

### 3) * Minimum Standards

**1) Does the pharmacy have internet access to current federal and state laws, regulations, and rules governing the legal distribution of drugs in Ohio?**

Yes

**2) Does the pharmacy have access to the telephone number of a poison control center?**

Yes

**3) Are the pharmacy's hours publicly posted?**

Yes

**4) Are all pharmacy staff wearing name tags/badges that include the employee's job title?**

Yes

**7) Are the library and equipment housed in a suitable, well-lit and well-ventilated room or department and maintained in a clean, sanitary and orderly condition?**

Yes

**8) Are areas where drugs and devices are stored and prepared dry, well-lit, well-ventilated, and maintained in a clean, sanitary and orderly condition?**

Yes

**9) Are storage areas maintained at temperatures and conditions which will ensure the integrity of the drug stock?**

Yes

## 4) Personnel

**1) Are staff working at the pharmacy properly licensed/registered with the Board?**

Yes

**5) Are certified pharmacy technicians working within their applicable scope of practice?**

Yes

**8) Are pharmacy support personnel working within their permitted scope?**

Not Applicable - No support personnel working or employed during inspection.

Observation

List of support personnel responsibilities: www.pharmacy.ohio.gov/supportres

**OAC 4729:3-1-01 (Z)**

(1) An individual employed or performing contracted services at a location licensed as a terminal distributor of dangerous drugs, trained to perform clerical duties associated with the practice of pharmacy, including pricing, cashiering, drug purchasing, delivering, scheduling deliveries, answering non-professional telephone inquiries, transportation of dispensed medications within a hospital, documenting and processing third-party billing information for reimbursement, or any other activity as determined by the board.

(2) An individual contracted by a terminal distributor of dangerous drugs to perform drug inventories.

(3) Except for those responsible for the delivery of dangerous drugs, support personnel shall not have unsupervised access to dangerous drugs.

(4) Support personnel shall not perform the tasks of a pharmacist, pharmacy intern, certified pharmacy technician, registered pharmacy technician, or pharmacy technician trainee.

(5) Support personnel may have access to or retrieve information from patient records, including a database or patient profile to perform clerical duties associated with the practice of pharmacy. Support personnel shall not enter prescription information into a patient profile.

(6) Support personnel may perform the following:

(a) Transporting dangerous drugs from a loading dock, warehouse or other area that receives shipments from a licensed wholesaler or other person licensed in accordance with section 4729.52 of the Revised Code; and

(b) Stocking and retrieving from inventory non-controlled dangerous drugs that are not dispensed by the pharmacy.

(7) The terminal distributor of dangerous drugs shall be responsible for ensuring all support personnel comply with state and federal requirements to ensure the confidentiality of patient health records.

(8) Stocking of automated drug dispensing units and floor stock with intravenous fluids that are non-controlled dangerous drugs and are not dispensed by an institutional pharmacy.*

(9) Overwrapping/placing in plastic dangerous drugs that have been compounded or dispensed (i.e. appropriately labeled) by a terminal distributor of dangerous drugs.*

(10) Entering demographic and insurance information into a patient's profile.*

## 10) Drug Purchases

**1) Does the licensee maintain complete and accurate records of drugs purchased?**

Yes

Observation
Wholesalers:

- McKesson
- TopRx
- Keysource
- Anda

**2) Has the licensee performed and documented an annual query of eLicense prior to purchasing drugs at wholesale?**

Yes

## 11) * Security, Control, and Storage of Dangerous Drugs

**1) Is a pharmacist providing supervision of the dangerous drugs, hypodermics, D.E.A. controlled substance order forms, and all records relating to the distribution of dangerous drugs in the pharmacy?**

Yes

**3) Are all dangerous drugs, controlled substances, and hypodermics that are delivered onto the premises of the store or business are immediately placed and secured in the pharmacy under the physical control?**

Yes

**4) Are there any unauthorized persons present in the pharmacy?**

No

**7) Can the pharmacy be secured by a physical barrier or alarm system?**

Yes

Observation
The only change to the barricade since March 2022 inspection was the replacement of the garage-style door. Door was replaced with a metal roll down bay-style door. Door is secured by the alarm system. No other changes to the barricade have been made since inspection in March 2022. Barricade is adequate.

**8) Is a licensed pharmacist the only person with access to keys or other methods for accessing the pharmacy?**

Yes

**10) Does the pharmacy have a secure area only accessible by pharmacists for customers to deposit new or refill prescription orders when the pharmacy is closed?**

No - Not applicable

**11) Does the pharmacy maintain dangerous drugs or hypodermics outside of the confines of the pharmacy?**

No

**12) Does the pharmacy provide services by means of a secured drive-through facility?**

No

## 12) Temperature Controls

**1) Are refrigerators and/or freezers used for the storage of drugs maintained at the proper temperature?**

Yes

Observation
Pharmacy has one refrigerator for vaccine storage. Pharmacy uses TempAlert to monitor the temperature of the refrigerator. Observed refrigerator to be at appropriate temperature. Pharmacy does not have vaccine stock or any refrigerator/freezer drug stock on site at the time of inspection.

**2) Does the pharmacy have a policy to respond to any out of range individual temperature readings or excursions to ensure the integrity of stored drugs?**

Yes

**3) Are refrigerators and freezers use for the storage of drugs free of food or beverage products?**

No

## 13) *Theft or Significant Loss of Drugs and Drug Documents

**1) Has the licensee experienced any theft or significant loss of any dangerous drugs in the past twenty-four months?**

No

**3) REMINDER: Theft or significant loss of dangerous drugs and drug documents.**

Observation
**REMINDER**

A licensee is required to report to the the Board and law enforcement authorities of any theft or significant loss of dangerous drugs (controlled and non-controlled prescription drugs) immediately upon discovery of the theft or significant loss. This includes dangerous drugs in transit that were either shipped from or to a prescriber, terminal distributor, or drug distributor.

A licensee is required to report, immediately upon discovery, to the Board and law enforcement authorities any theft or loss of uncompleted prescription blank(s) used for writing a prescription, D.E.A. controlled substance order forms (Form 222), written prescription order(s) not yet dispensed, and original prescription order(s) that have been dispensed.

For more information on reporting, visit: www.pharmacy.ohio.gov/theft

## 14) * Controlled Substance Inventory

**1) Does the licensee conduct an annual inventory of controlled substances?**

Yes

Observation
Pharmacy does not have any controlled substance drug stock on site at the time of inspection.
**OAC 4729:5-3-07**
All Category III licensees must complete an annual inventory even if drugs are not on-site (zero balance). Records of inventories must be maintained for at least three years. Inventories must follow the process for conducting a DEA controlled substance inventory.

## 16) Drug Collection Receptacles

**1) Does the pharmacy operate a drug take back program (i.e. collection receptacle)?**

No

## 17) Drug Samples

**1) Does the pharmacy have sample drugs as part its inventory?**

No

## 23) Return to Stock

**4) Does the pharmacy use delivery agents?**

Yes - Compliant

Observation
Pharmacy uses USPS, UPS, and FedEx. Pharmacy does not return any delivered drugs back to stock for redispensing. All drug stock returned from delivery agents are sent to Inmar for destruction.

**8) REMINDER: The contents of a prescription vial or container shall not be returned to the manufacturer's stock bottle.**

Observation
REMINDER: The contents of a prescription vial or container shall not be returned to the manufacturer's stock bottle.
OAC 4729:5-5-22 (B)(4)

## 25) Customized Medication Packaging (Adherence Packaging)

**1) Does the pharmacy dispense customized patient medication packages (sometimes referred to as adherence packaging)?**

No

## 27) Charitable Pharmacies

**1) Is this pharmacy a charitable pharmacy?**

No

## 31) *Expired/Adulterated Drugs

**2) Are there expired/adulterated drugs present in the licensee's active drug stock?**

No

### 33) Prescription Pick-Up Station

**1) Does the pharmacy accept prescriptions from pick-up stations or other intermediaries?**

No

### 39) Drug Repository Program

**1) Does this pharmacy operate a drug repository program?**

No

### 40) Temporary Removal of Drugs

**1) Does the licensee engage in the temporary off-site storage of dangerous drugs?**

No

### 46) Substance Abuse and Mental Health Resources for Healthcare Professionals

**1) Substance Abuse and Mental Health Resources for Healthcare Professionals**

Observation

The healthcare profession is not immune to substance use disorder and mental health conditions. Such medical conditions impair a healthcare professional's competency, ability, and judgment. Substance use disorder and/or mental health conditions that are left untreated may not only cause a healthcare professional to risk their career, but may also endanger the life of a patient.

These medical conditions can be effectively treated, and it is possible for healthcare professionals that are in treatment or recovery to return to practice.

The State of Ohio Boar of Pharmacy encourages all healthcare professionals who may be struggling with substance use disorder or mental health condition to seek help. The following are resources that can assist healthcare professionals in getting help: (the resources listed here are for informational purposes only and do not constitute an endorsement by the State of Ohio Board of Pharmacy. They do not represent a complete list of the resources available)

Ohio Careline 1-800-720-9616, emotional support, with referral to other resources if needed.
Crisis text line, text "4hope" to 741 741 to speak with a crisis counselor.
Treatment Bridge 1-877-275-6364, for addiction and mental health srevices.
National Suicide prevention dial 988, or call 1-800-273-8255.
Ohio Domestic Violence Network 1-800-934-9840
Pharmacist Rehabilitation Organization (www.ohiopro.org) for pharmacists and pharmacy interns.
Ohio Physicians Health Program (www.ophp.org)

### 50) Inspection Affirmation

**1) Inspection Affirmation**

Observation

As the person in charge at the time of this inspection, I affirm that I have reviewed this inspection report with the Specialist/Agent/Inspector, and understand its content.

If this inspection report requires a written response, I understand, per OAC 4729:5-3-03, that either of the following must be submitted to the State of Ohio Board of Pharmacy within 30 days of this inspection:

(1) The action(s) the licensee or applicant has taken to correct the violation(s) and the date of implementation of the corrective action(s); or

(2) An explanation disputing the observed violations.

I understand that if I am not the responsible person documented on this site's Ohio terminal distributor of dangerous drugs license, I will ensure the responsible person is provided a complete copy of this inspection report in a timely manner.

I further acknowledge that a written response does not release the licensee listed in this inspection report from potential disciplinary action.

Responses must be either emailed (with a copy of the inspection report) to writtenresponse@pharmacy.ohio.gov or mailed to 77 South High Street, 17th Floor, Columbus, Ohio 43215.

## Summary

**No Issue Found**

**Reviewed by** Christopher Spitzer, R.Ph. _____

(signature)

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| FS1293884 | 02-28-2025 | $888 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,2N,3, 3N,4,5 | RETAIL PHARMACY | 03-23-2022 |

SEVEN HILLS PHARMACY LLC
2722 E. KEMPER RD
SHARONVILLE, OH 45241

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

**THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.**

**CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE**
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
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SEVEN HILLS PHARMACY LLC
2722 E. KEMPER RD
SHARONVILLE, OH 45241

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THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

Truepill
CA old license PHY 56100
ME old license MO40002429
NC old license 13413
LA license PHY.007761-NR

**Louisiana Board of Pharmacy**

The Louisiana Board of Pharmacy issued the pharmacy a Consent Order of Discipline dated May 11, 2022. The pharmacy did not report the change of ownership in a timely manner. The Louisiana Board of Pharmacy approved the change of ownership application with a new permit number PHY.008479-NR as a successor to permit number PHY.007761-NR.

**North Carolina Board of Pharmacy**

The North Carolina Board of Pharmacy issued the pharmacy a Consent Order of Discipline dated March 8, 2022. The pharmacy made inaccurate statements about its ownership and officers on its initial application in November 2017 and did not correct this until November 2021. The North Carolina Board of Pharmacy approved the change of ownership application with a new permit number 14900 as a successor to permit number 13413.

**Maine Board of Pharmacy**

The Maine Board of Pharmacy notified the pharmacy on March 30, 2022 that its non-resident license was terminated effective November 6, 2019 for reporting deficiencies related to its ownership. The pharmacy submitted a change of ownership application for licensure, and has been issued a new pharmacy license on November 2, 2022.

**California Board of Pharmacy**

The California Board of Pharmacy issued the pharmacy a letter of admonishment CI 2019 84877 dated January 23, 2020, concluding an investigation that found the pharmacy shipped a prescription to the wrong patient and shipped two prescriptions with the wrong return address.

The California Board of Pharmacy issued the pharmacy a modified citation and fine CI 2019 78633 dated June 16, 2020, with the fine amount of $0.00. In 2018, certain prescriptions were issued to the pharmacy by prescribers that were either not yet licensed to prescribe in California or who had not yet entered into an established standardized procedure or protocol developed by a supervising physician.

Also, The California Board of Pharmacy issued the pharmacy a citation and fine order of abatement CI 2020 89223 dated August 25, 2021, with the fine amount of $5,000. The pharmacy was in violation when dangerous drugs were stored in temperatures exceeding the recommended storage temperatures Truepill did not consider the manufacturer's stability data for drugs which may have been adulterated by heat.

# BOARD OF PHARMACY
# DEPARTMENT OF CONSUMER AFFAIRS
# STATE OF CALIFORNIA

# MODIFIED CITATION AND FINE

| Citation Number | Name, License No |
|---|---|
| CI 2017 78633 | TRUEPILL (FORMERLY POSTMEDS INC.), PHY 56100 |

**JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)**

| VIOLATION CODE SECTION | OFFENSE | AMT OF FINE |
|---|---|---|
| Bus. & Prof. Code § 4059 subd. (a)/Bus. & Prof. Code § 4067 subd. (a) | Furnishing dangerous drugs without a prescription/Internet; Dispensing Dangerous Drugs or Devices without Prescription; No person shall dispense or furnish, or cause to be furnished dangerous drugs...on the internet...without a prescription issued pursuant to a good faith examination | Citation without a fine |
| Bus. & Prof. Code § 4174 | Dispensing on order of nurse practitioner or person of similar status. | Citation without a fine |

CONDUCT:

Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Business and Professions Code 4059 (a) states in pertinent part a person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. In conjunction with Business and Professions Code 4067 (a) which states no person or entity shall dispense or furnish, or cause to be dispensed or furnished, dangerous drugs or dangerous devices, as defined in Section 4022, on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination of a human or animal for whom the prescription is meant if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination of a human or animal, or if the person or entity did not act in accordance with Section 1761 of Title 16 of the California Code of Regulations and (f) for the purposes of this section, "good faith prior examination" includes the requirements for a physician and surgeon in Section 2242. In conjunction with Business and Professions Code 2290.5 (a) For purposes of this division, the following definitions shall apply: (3) "Health care provider" means either of the following: (A) a person who is licensed under this division. Between 4/1/2018 to 10/31/2018, Postmeds Inc. (PHY56100) located at 3121 Diablo Ave. Hayward, CA dispensed prescriptions issued by prescribers who were not licensed in California. Specifically, 2 prescriptions were issued by Nurse Practitioner Jenny Ingle; 9 prescriptions were issued by Dr. Brook Randal; 6 prescriptions were issued by Dr. Jessica Rubino and 4 prescriptions were issued by Dr. Sudhi Trye. These prescribers were not licensed in California at the time the prescriptions were initiated and shipped to a California resident. Postmeds pharmacy dispensed the prescriptions issued by unlicensed prescribers to

California residents in violation of Business and Professions Code 4059 (a) and Business and Professions Code 4067 (a).

Dispensing by Pharmacist Upon Order of Nurse Practitioner: Business and Professions Code 4174 states in pertinent part notwithstanding any other law, a pharmacist may dispense drugs or devices upon the drug order of a nurse practitioner functioning pursuant to Section 2836.1 or a certified nurse-midwife functioning pursuant to Section 2746.51, a drug order of a physician assistant functioning pursuant to Section 3502.1 or a naturopathic doctor functioning pursuant to Section 3640.5, or the order of a pharmacist acting under Section 4052.1, 4052.2, 4052.3, or 4052.6. Postmeds Inc. (PHY56100) located at 3121 Diablo Ave. Hayward, CA dispensed prescriptions issued by Nurse Practitioners and Physicians Assistants who had not yet entered into an established standardized procedure or protocol developed by a supervising physician. Between 4/1/2018 and 10/31/2018, the following prescribers issued prescriptions to Postmeds without an established protocol in place: Physician's Assistant Leanne Mays issued 8 prescriptions and Physician's Assistant Susan Owen issued 6 prescriptions. Between 4/1/2018 and 10/31/2018, the following prescribers issued prescriptions to Postmeds entering into a protocol after the prescriptions were issued: Nurse Practitioner Joni Gunzburger issued 4,782 prescriptions; Nurse Practitioner Cristin Hackel issued 10,819 prescriptions and Nurse Practitioner Jessica Horwitz issued 4,711 prescriptions. Postmeds Pharmacy dispensed the prescriptions issued by Nurse Practitioners and Physicians Assistants who had not yet entered into standardized procedures or protocols as required by Business and Professions Code 4174.

| | |
|---|---|
| **CITATION ISSUED ON: June 16, 2020** | **TOTAL AMOUNT OF FINE(S): $0.00** |
| **PAYMENT OF FINE(S) DUE BY: July 16, 2020** | |

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

January 23, 2020

VIA CERTIFIED MAIL

**LETTER OF ADMONISHMENT**

TRUEPILL
ATTN: MOHAMMAD UMAR AFRIDI, CEO
3121 DIABLO AVE
HAYWARD, CA 94545

**RE: CI 2019 84877**
**TRUEPILL**
**PHY 56100**

This LETTER OF ADMONISHMENT is being issued pursuant to Business and Professions Code section 4315 for failure to comply with the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the board's website at www.pharmacy.ca.gov, under Forms and Publications.)

The Board of Pharmacy has completed its investigation in the above referenced matter. All documentation and/or statements relating to the investigation have been accepted and included in an Investigation Report on file in this office. Facts contained in this report lead to the conclusion that the following violations of pharmacy laws or regulations have occurred:

**JURISDICTION: Bus. & Prof. Code § 4315; 1764/56.10(a) - Unauthorized disclosure of prescription and medical information**

Unauthorized disclosure of prescriptions: California Code of Regulations section 1764 states in pertinent part that no pharmacist shall exhibit, discuss, or reveal the contents of any prescription or any medical information furnished by the prescriber with any person other than the patient or his or her authorized representative and Civil Code section 56.10 subdivision (a) states, in pertinent part, no provider of health care shall disclose medical information regarding a patient of the provider of health care without first obtaining an authorization. Truepill Pharmacy was not in compliance with these regulations. Specifically, on 4/17/2019, Truepill Pharmacy (PHY56100) located at 3121 Diablo Avenue in Hayward, CA shipped prescription RX#1186395 to the wrong person. The prescription was intended for AR but was shipped to the address of MS in error. Also, Truepill Pharmacy shipped prescriptions to patients with a shipping label showing the return address of NuRx located at 6838 Ellicott Drive in East Syracuse, NY and from Apostrophe located at 330 2nd Street in Oakland, CA. NuRx and Apostrophe are not licensed pharmacies and prescription packages returned as undeliverable to these locations would cause the disclosure of medical information without authorization.

Shipping prescriptions to an unauthorized person violates California Code of Regulations section 1764 and Civil Code 56.10.

If you wish to contest this Letter of Admonishment, you may do so by submitting, within 30 days of the date of service of this Letter of Admonishment, namely February 22, 2020, the attached "Request for an Office Conference" form. If an office conference is not requested, compliance with the Letter of Admonishment shall not constitute an admission of the violations described in the Letter of Admonishment.

Unless it is dismissed following an office conference or you receive other instructions from the Board in writing, Pharmacy Law requires that you maintain and have readily available for inspection a copy of this Letter of Admonishment and any written corrective action plan, if any, for at least three years from the date of issuance at the top of this letter. The Letter of Admonishment will be considered a public record for purposes of disclosure for three years from issuance. The issuance of this Letter of Admonishment does not limit the board's ability to pursue other disciplinary or administrative action under Business and Professions Code section 4315, subdivision (f).

If you have any questions regarding this Letter of Admonishment, please contact Barbera Schleicher, Public Inquiry Analyst at (916) 518-3081.

Sincerely

Virginia Herold

Virginia Herold
Executive Officer
Board of Pharmacy

**California State Board of Pharmacy**
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

August 25, 2021

TRUEPILL
ATTN: FRANCESCO CONSOLE, PIC
3121 DIABLO AVE
HAYWARD, CA 94545

**RE: CI 2020 89223**
**TRUEPILL**
**PHY 56100**

The attached Citation CI 2020 89223, has been issued to TRUEPILL, PHY 56100. A copy has been sent to the pharmacy, and a copy is being sent to the pharmacist-in-charge for informational purposes only. As pharmacist in charge it is your responsibility to insure the pharmacy's compliance with the term(s) and condition(s) of the citation by the date(s) ordered, and to ensure the pharmacy's compliance with all pharmacy laws.

The Citation references the specific statutes and regulations violated, and defines each violation charged. The Citation details the conduct that resulted in the issuance of the citation. In addition the citation may also include information regarding fine(s) assessed. If fine(s) have been assessed, the citation specifies the amount and the specific violation for which the fine was levied.

If you have any questions please contact Joshua Monforte, Citation and Fine Analyst at (916) 518-3014.

Sincerely

Joshua Monforte
Citation and Fine Analyst

Attachments

# BOARD OF PHARMACY
# DEPARTMENT OF CONSUMER AFFAIRS
# STATE OF CALIFORNIA

# CITATION AND FINE
# ORDER OF ABATEMENT

COPY

| Citation Number | Name, License No |
|---|---|
| CI 2020 89223 | TRUEPILL, PHY 56100 |

**JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)**

| VIOLATION CODE SECTION | OFFENSE | AMT OF FINE |
|---|---|---|
| CCR, Title 16, § 1714 subd. (b) | Operational Standards and Security; pharmacy responsible for pharmacy security | $5,000.00 |
| Bus. & Prof. Code § 4169 subd. (a)(2)/Health & Safety Code § 111295 | Prohibited Acts; Purchase, trade, sell, or transfer dangerous drugs to that the person knew or reasonably should have known were adulterated.../It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated | Citation without a fine |

CONDUCT:

California Code of Regulations 1714, section b states, (b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy. Specifically, Truepill Pharmacy, PHY56100, located at 3121 Diablo Ave, Hayward, CA 94545 was in violation when they failed to keep dangerous drugs stored according to policy and procedure 2001.4, Oversight of Pharmacy Safety, which states: "The Pharmacy will make all attempts at maintaining a room temperature below 85F and ideally between 68-77F". Between 7/1/2020 and 9/14/2020, on numerous occasions, dangerous drug storage temperatures, summarized in Table 2, exceeded the recommended storage temperatures. The most egregious of these temperature spikes were:

a)On 8/13/2020, in the cage area of the warehouse, dangerous drugs were stored approximately 161 hours over 77 F and 47 hours over 85F.
b)On 9/6/2020, in the cage area of the warehouse, dangerous drugs were stored approximately 59 hours over 77 F and 17 hours above 85F.
c)On 8/13/2020, in the Parata Automated dispensing machine located in the warehouse, dangerous drugs were stored for approximately 163 hours above 77 F and 44 hours above 85 F.

Business and Professions Code 4169 section (a), subdivision (2) states, A person or entity shall not do any of the following: (2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code as it relates to Health and Safety Code 111295 which states, It is unlawful for any person to manufacture, sell, deliver, hold or offer for sale any drug or device that is adulterated. Specifically, Truepill Pharmacy, PHY56100, located at3121 Diablo Ave, Hayward, CA 94545 was in violation when they used the MKT calculation alone instead of in conjunction with manufactures stability data as stated in USP <1079>, which provides guidance for assessing possible adulteration to dangerous drugs stored at the pharmacy due to excessive heat. In particular, USP<1079> states, "Knowing the MKT for an excursion is useful for evaluating the potential impact on product quality. However, it is also essential to know the upper and lower temperature limits of any excursion. If these extreme temperatures are outside available stability data, it may not be possible to predict the quality impact of the excursion with any confidence regardless of the MKT. At higher temperatures the kinetics of degradation may change or new degradation reactions may occur. Truepill Pharmacy did not consider the manufacture's stability data for at least 72 dangerous drugs stored in the cage area of the warehouse which were held and offered for sale when determining if a dangerous drug was adulterated by the extreme heat, summarized in Table 3. For each one of the 72 dangerous drugs, the maximum temperature for storage was listed by the manufacturer as 77F or storage information was not listed. As there was no stability temperature for at least the 72 drugs in question and per USP<1079>, the MKT cannot be without the stability data, these drugs which were held and offered for sale were adulterated.

## ORDER OF ABATEMENT

By the Abatement date/payment date submit to the Board the following:

- Either (1) full payment of the assessed fine(s) in the amount of $5,000.00; or payment in the amount of $1,000.00 and (2) provide proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within ninety (90) days.

COPY

If you choose option (2), within 90 days of this citation, you shall submit proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations. Any failure to do so shall be deemed a failure to meet the abatement requirements of this citation.

If you timely submit proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within 90 days from the date the citation was issued, this citation shall be reduced to $1,000.00 and proof of compliance of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations shall be considered satisfactory abatement of the citation.

If you fail to submit proof of compliance of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within 90 days from the date the citation was issued, the stay shall be lifted and the fine(s) in the amount of $5,000.00 shall be due and owing from you within thirty (30) days of any such failure.

| CITATION ISSUED ON: August 25, 2021 | TOTAL AMOUNT OF FINE(S): $5,000.00 |
|---|---|

**PROOF OF ABATEMENT AND PAYMENT OF FINE(S) DUE BY: September 24, 2021**

COPY

**LOUISIANA BOARD OF PHARMACY**

**BATON ROUGE, LOUISIANA**

**IN THE MATTER OF:** **CONSENT ORDER**

**POSTMEDS, INC.**

**LOUISIANA PHARMACY PERMIT NO. 7761** **Case No. 21-0456**

**********

## CONSENT AGREEMENT

WHEREAS, an informal conference was conducted by the Violations Committee of the Louisiana Board of Pharmacy (hereinafter referred to as the "Board") on March 16, 2022 at the Board office, 3388 Brentwood Drive, Baton Rouge, LA 70809, in the matter of POSTMEDS, INC. (hereinafter referred to as "Respondent"), holding Louisiana Pharmacy Permit No. 7761, 3121 Diablo Ave., Hayward, CA 94545-2701, with attorney Skip Philips and Postmeds Corporate Counsel Donnie Simkin appearing on behalf of Respondent.

WHEREAS, WHEREAS, on August 27, 2018, the Louisiana Board of Pharmacy issued a non-resident pharmacy permit, PHY.007761-NR, to Postmeds Inc. At that time, Postmeds Inc. was 31.5% owned by Mohammad Umar Afridi, 31.5% owned by Siddharth Viswanathan, 16.5% owned by Initialized III L.P., and 20.5% owned by others with no individual owner holding more than 4%. On December 17, 2021 the Board received an "Application for New Louisiana Pharmacy Permit for Nonresident Pharmacy" from Postmeds, Inc. d/b/a Truepill. Accompanying correspondence and organization chart detailed a 100% change in the ownership structure of Postmeds Inc., effective November 6, 2019. Postmeds Inc. went from being owned 31.5% by Mohammad Umar Afridi, 31.5% by Siddharth Viswanathan, 16.5% by Initialized III L.P., and 20.5% by others with no individual owner holding more than 4%, to being owned 100% by Truepill, Inc.

WHEREAS, the Board alleges that such actions constitute violations of the following:

**La. R.S. 37:1241 (A)(1):** Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

**La. R.S. 37:1221(B).** No out-of-state pharmacy providing pharmacy services to residents of this state shall open, establish, operate, or maintain a pharmacy, located out-of-state, unless the pharmacy is issued a permit by the board.

**La. R.S. 37:1222(A).** A person applying for a permit to open, establish, operate, or maintain a pharmacy, within or outside of this state, shall complete an application in such form and contain such data as the board may require, and complete such other requirements as deemed necessary by the board, including but not limited to designation and identification of a pharmacist-in-charge.

**La. R.S. 37:1222(E).** A permit to operate a pharmacy shall not be transferable.

**La. R.S. 37:1232(A).** A pharmacy located outside this state which does business in this state within the meaning of this Chapter, shall hold a current pharmacy permit as provided in this Chapter. The pharmacy shall be designated a "nonresident pharmacy" and the permit shall be designated a "nonresident pharmacy permit."

**LAC, Title 46: LIII §1101(A).** Individuals, partnerships, corporations, limited liability companies, or associations desiring to operate a pharmacy in Louisiana, or outside the state where prescriptions drugs/devices are dispensed and delivered to Louisiana residents, shall execute an application for a pharmacy permit for their particular classification of pharmacy.

**LAC, Title 46: LIII §1135(A)(1)(e).** The holder of a pharmacy permit shall notify the board, in writing, prior to the transfer of ownership, in order for the board to complete an inspection of the pharmacy premises. A change of ownership of a pharmacy is evident under the following conditions: a 50 percent, or more, change in ownership of a corporation, limited liability company, or association since the issuance of the original permit or the last renewal application.

**LAC, Title 46: LIII §1135(A)(2).** The new owner(s) of the pharmacy shall submit a properly completed pharmacy permit application, with appropriate fee, to the board.

**LAC, Title 46: LIII §1135(A)(4).** Pharmacy permits are not transferable from the original holder(s) of the permit to the new owner(s).

**LAC, Title 46: LIII §2305(A).** The out-of-state pharmacy shall apply for a permit and annual permit renewals on forms provided by the board.

**LAC, Title 46: LIII §2307(C). Authority and Accountability**. The designated pharmacist-in-charge of the pharmacy and the pharmacy owner(s), or partners, or corporate officer(s) of the permit holder, where applicable, shall be responsible for the complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.

To facilitate the submission of this Consent Agreement, Respondent does not contest the allegations and agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

**POSTMEDS, INC., holder of Louisiana Pharmacy Permit No. 7761, is ordered to pay a fine of $10,000.00 and to reimburse the Board $250.00 for administrative costs, and $324.48 for investigative costs with total payment due the Board of $10,574.80, due by *certified check or money order* to be paid simultaneously with the execution of this Consent Agreement by Respondent.**

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter, waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing and to judicial review of this Consent Agreement. Moreover, at no time shall Respondent request the expungement, rescission or removal of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting. However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon its authorized representative signing said Order.

Respondent agrees to authorize the Board to report this action to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as required by law.

I, Matt Davis-Ratner, authorized to act on behalf of and acting on behalf of **POSTMEDS, INC.**, understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of this case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

[*Remainder of page intentionally left blank; signature page to follow.*]

SIGNED, AGREED TO AND ENTERED ON THIS 6th DAY OF April, 2022.

**POSTMEDS, INC.**
**Louisiana Pharmacy Permit No. 7761**

Matt Davis-Ratner

BY: Matt Davis-Ratner
Authorized Representative

Harry J. Philips

HARRY J. "SKIP" PHILIPS
Taylor Porter
450 Laurel St, 8th Floor
Baton Rouge, LA 70801
*Attorney for Respondent*

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

Carlos Finalet

CARLOS M. FINALET, III
*General Counsel, Louisiana Board of Pharmacy*

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on May 11, **2022**, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Marty R McKay

Marty R. McKay
Hearing Officer for the Board

svb

Silicon Valley Bank

3003 Tasman
Santa Clara, California 95054
408-654-7400

90-4039
1211

**CASHIER'S CHECK** No. 208457

Remitter: **Postmeds, Inc.**
**Permit No. 7761**

| Date | Check No. | Amount |
|---|---|---|
| Apr 13,2022 | 208457 | $10,574.80 |

*PAY EXACTLY*
*** **Ten Thousand Five Hundred Seventy-Four and 80/100** **Dollars**

TWO SIGNATURES REQUIRED OVER $50,000.00

Pay to the order of: **Louisiana Board of Pharmacy**

⑈208457⑈ ⑆121140399⑆ 7899900470⑈

**STATE OF NORTH CAROLINA**
**NORTH CAROLINA BOARD OF PHARMACY**

| | | |
|---|---|---|
| **IN THE MATTER OF** | ) | |
| | ) | |
| **POSTMEDS, INC. d/b/a Truepill,** | ) | **CONSENT ORDER** |
| | ) | **OF DISCIPLINE** |
| **Permit No. 13413 and Its Successor Permit(s).** | ) | |

THIS MATTER came to be considered before a member of the North Carolina Board of Pharmacy (hereinafter, the "Board") pursuant to 21 N.C.A.C. 46 .2008. The Conference was scheduled for Thursday, February 24, 2022, and, after appropriate notice, was heard on that day by Board member Wallace E. Nelson. Respondent PostMeds, Inc. was informed of its right to be present at the pre-hearing conference and declined. The Board's General Counsel, Clinton R. Pinyan, represented the Board.

Respondent has agreed to waive a formal hearing in the above-referenced matter. It stipulates and agrees to the findings of fact and conclusions of law recited herein and to the order of discipline imposed. By its consent, Respondent also stipulates that it waives its right to appeal this Consent Order or challenge in any way the sufficiency of the findings of this Order as a basis for the action taken. Based upon the consent of the parties, the Board hereby enters the following:

## FINDINGS OF FACT

1. On November 20, 2017, the Board issued Permit No. 13413 to Respondent PostMeds, Inc. d/b/a Truepill (Permit No. 13413) ("PostMeds").

2. On PostMeds' initial permit application, its then-pharmacist manager, Mohammad Umar Afridi, submitted an inaccurate statement that he was the sole owner and officer of PostMeds. In fact, PostMeds now acknowledges that Afridi and Siddharth

Viswanathan each owned 47 percent of PostMeds on November 20, 2017, with others owning six percent, and that Viswanathan was also an officer of PostMeds.

3. Viswanathan and the minority owners' interests would not have raised questions about the permit application in this particular case. If PostMeds had disclosed the true ownership and officers of PostMeds, the Board still would have granted PostMeds a permit. However, it was an inaccurate statement that Afridi, as the person who submitted the application, knew was inaccurate. That statement prevented the Board from vetting Viswanathan as the owner of the pharmacy. Because of the inaccuracy of the representations, the initial permit was void ab initio.

4. In November 2019, PostMeds went through a corporate restructuring. During that restructuring, Truepill, Inc. was created as a holding company for PostMeds. At that time, Truepill, Inc. became the sole owner of PostMeds. Afridi, Viswanathan and the other former direct owners of PostMeds became indirect owners with the same ownership interests in the holding company, Truepill, Inc., that they had before the transfer of ownership.

5. This restructuring required PostMeds to submit a transfer of ownership application and have that application granted before the restructuring closed. PostMeds failed to do this. Therefore, even if the initial permit had been valid (which it was not), it would have become invalid upon the corporate restructuring.

6. Insertion of a new holding company between the ultimate owners and PostMeds would not have raised questions about the permit application in this particular case. The ownership interests of the ultimate owners did not change. If PostMeds had disclosed the new holding company, the Board still would have granted the transfer of ownership. However,

PostMeds failed to submit the transfer of ownership application or otherwise disclose the interests of Truepill, Inc.

7. In each of its subsequent renewals, PostMeds failed to correct the ownership information that it had inaccurately submitted on its initial application or to list Truepill, Inc., as the direct owner of the pharmacy.

8. On November 4, 2021, counsel for PostMeds informed the Board that its "current ownership information on file with the North Carolina Board of Pharmacy is out of date." Upon follow-up questioning, the next day, PostMeds disclosed that it should have submitted a transfer of ownership application in November 2019. It further was apparent from the ownership information that PostMeds provided that Afridi made inaccurate representations about ownership and officers on PostMed's initial application that had never been corrected.

9. PostMeds agreed to stop shipping any drugs, devices or medical equipment into the State of North Carolina until the matter was resolved. It further agreed to stop shipping or dispensing any drugs, devices or medical equipment from six other pharmacies under its ownership until the matter was resolved (even though those pharmacies did not receive permits until after the transfer of ownership had occurred, and so did not suffer from the same problem).

10. PostMeds submitted a transfer of ownership application promptly.

11. Although PostMed's disclosure of its inaccuracies was tardy, its remedial actions are a mitigating factor in this matter.

## CONCLUSIONS OF LAW

1. Reporting of correct and complete ownership information on an initial pharmacy permit application or a renewal application is material, indeed essential, to the Board's ability to ensure that a pharmacy will provide services safely and competently to the public.

2. PostMeds made inaccurate statements about its ownership and officers on its initial application, which it failed to correct at any point through its 2022 renewal. That initial permit was therefore void ab initio and violated G.S. § 90-85.38(b).

3. The creation of Truepill, Inc. as a holding company further triggered a requirement to report the ownership change and obtain a successor permit, and to do so before the closing of the transaction that created Truepill, Inc. The transaction "result[ed] in a different person . . . owning more than 50 percent interest in the permit holder . . . ." 21 NCAC 46.1603. Failure to apply for and obtain a successor permit prior to the transaction, and a continuing failure to disclose the ownership interest of Truepill, Inc., violated G.S. § 90-85.38(b).

**IT IS THEREFORE ORDERED**:

PostMeds was in violation of G.S. § 90-85.38(b) in North Carolina from November 20, 2017 until at least November 4, 2021. Respondent PostMed's Permit No. 13413 was **VOID** from the time that it was granted on November 20, 2017. G.S. § 90-85.38(c).

Respondent PostMed's change of ownership application is **APPROVED** as a successor permits to Permit No. 13413 (the "Successor Permit") with the following **CONDITIONS**:

1. PostMeds shall provide timely advance notice of any contemplated change in ownership to the current pharmacist-manager and any future pharmacist-manager(s) of the Successor Permit. PostMeds shall consult with the Successor Permit's pharmacist-manager(s) to determine whether any contemplated transaction triggers the need to obtain new permits. PostMeds shall authorize the Successor Permit's pharmacist-manager(s) to take any necessary action to update that ownership information with the Board or to apply for new permits. If a contemplated transaction triggers the need for new permits, PostMeds shall not complete that

transaction unless and until either the Board issues new permits or PostMeds ceases all practice of pharmacy at the permitted location.

2. The Successor Permit shall violate no laws governing the practice of pharmacy or the distribution of drugs.

3. The Successor Permit shall violate no rules or regulations of the Board.

4. If the Successor Permit fail to comply with any term or condition of this Order, it may be subject to additional disciplinary action by the Board.

This is the 8th day of March, 2022

NORTH CAROLINA BOARD OF PHARMACY

By: /s/ William A. Mixon
William A. Mixon
President

Respondent PostMeds, Inc. has full knowledge that it has the right to a formal hearing, at which it would have the right to be represented at its expense by counsel, in this matter. Respondent freely, knowingly and voluntarily waives its right to such a hearing by entering into this Consent Order.

Respondent understands and agrees that by entering into this Consent Order, it certifies that it has read the foregoing Consent Order and that it voluntarily consents to the terms and conditions set forth therein and relinquishes any right to judicial review of Board actions that may be taken concerning this matter.

Respondent further understands that should it violate the terms and conditions of this Consent Order, the Board may take additional action.

Respondent understands and agrees that this Consent Order will not become effective unless and until approved by the Board.

Respondent understands that it has the right to have counsel of its choice review and advise them with respect to their rights and this Consent Order, and represents that it enters this Consent Order after consultation with counsel or after knowingly and voluntarily choosing not to consult with counsel. Respondent further agrees that the person who is executing this Consent Order has been duly authorized by any required corporation action to execute on behalf of Respondent.

CONSENTED TO BY:

M-1 Date 3/7/22

Printed Name: Matt Davis-Ratner

Title: General Counsel

STATE OF _____

_____ COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that the above-named representative of PostMeds, Inc. personally appeared before me this day, and acknowledged the due execution of the foregoing document.

Date: _____

_____
Notary Public

_____

My commission expires: _____

Truepill
CA old license PHY 56100
ME old license MO40002429
NC old license 13413
LA license PHY.007761-NR
KS license 22-117859
DEA license FP6189725

**DEA Order to Show Cause**
Although the matter remains pending and no discipline has issued, for transparency with the Board and out of an abundance of caution, the Pharmacy wishes to disclose that on December 15, 2022, the federal Drug Enforcement Agency ("DEA") issued the Pharmacy an administrative Order to Show Cause ("OSC") regarding revocation of its DEA registration FP6189725. On January 13, 2023, the Pharmacy answered the OSC.

**Kansas Board of Pharmacy**
The Kansas Board of Pharmacy issued the pharmacy an amended Summary Order effective February 8, 2023. The pharmacy did not report the change of ownership in a timely manner, and paid a fine. The Kansas Board of Pharmacy approved the change of ownership application, and issued license 22-117859 on May 20, 2022.

**Louisiana Board of Pharmacy**
The Louisiana Board of Pharmacy issued the pharmacy a Consent Order of Discipline dated May 11, 2022. The pharmacy did not report the change of ownership in a timely manner. The Louisiana Board of Pharmacy approved the change of ownership application with a new permit number PHY.008479-NR as a successor to permit number PHY.007761-NR.

**North Carolina Board of Pharmacy**

The North Carolina Board of Pharmacy issued the pharmacy a Consent Order of Discipline dated March 8, 2022. The pharmacy made inaccurate statements about its ownership and officers on its initial application in November 2017 and did not correct this until November 2021. The North Carolina Board of Pharmacy approved the change of ownership application with a new permit number 14900 as a successor to permit number 13413.

**Maine Board of Pharmacy**

The Maine Board of Pharmacy notified the pharmacy on March 30, 2022 that its non-resident license was terminated effective November 6, 2019 for reporting deficiencies related to its ownership. The pharmacy submitted a change of ownership application for licensure, and has been issued a new pharmacy license on November 2, 2022.

**California Board of Pharmacy**

The California Board of Pharmacy issued the pharmacy a letter of admonishment CI 2019 84877 dated January 23, 2020, concluding an investigation that found the pharmacy shipped a prescription to the wrong patient and shipped two prescriptions with the wrong return address.

The California Board of Pharmacy issued the pharmacy a modified citation and fine CI 2019 78633 dated June 16, 2020, with the fine amount of $0.00. In 2018, certain prescriptions were issued to the pharmacy

by prescribers that were either not yet licensed to prescribe in California or who had not yet entered into an established standardized procedure or protocol developed by a supervising physician.

Also, The California Board of Pharmacy issued the pharmacy a citation and fine order of abatement CI 2020 89223 dated August 25, 2021, with the fine amount of $5,000. The pharmacy was in violation when dangerous drugs were stored in temperatures exceeding the recommended storage temperatures Truepill did not consider the manufacturer's stability data for drugs which may have been adulterated by heat.

**U.S. Department of Justice**
**Drug Enforcement Administration**

www.dea.gov

Springfield, Virginia 22152

**IN THE MATTER OF**

Truepill
3121 Diablo Ave
Hayward, CA 94545

DEA Certificate of Registration FP6189725

**ORDER TO SHOW CAUSE**

Telemedicine is an important tool for providing increased access to medical treatment that has been relied upon by hundreds of millions of Americans since the onset of the COVID-19 pandemic in 2020. Unfortunately, this access is being exploited by a subset of medical practitioners and businesses seeking opportunities to profit by wrongfully providing controlled substances without a legitimate medical purpose.

DEA has an obligation to protect the public by ensuring that pharmacists only fill prescriptions for controlled substances which are prescribed for legitimate medical purposes by practitioners acting in the usual course of professional practice. It is critical that entities engaged in the practice of online pharmacy are appropriately registered and subject to reporting, disclosure, and other requirements imposed under law. These requirements allow entities engaged in the legitimate practice of telemedicine to continue safely providing critical services and protect the safety and health of the American public.

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act) and its implementing regulations prohibit actors from operating as an "online pharmacy" without the appropriate DEA registration. Truepill does not have the requisite registration to act as an online pharmacy. But since September 2020, it has acted as an online pharmacy, and in a two-year period filled 72,000 controlled substance prescriptions, of which 60% were for stimulants, such as amphetamines used in the treatment of Attention Deficit/Hyperactivity Disorder (ADHD).

Truepill was the pharmacy for telehealth companies, including Cerebral, that marketed ADHD treatments, including Adderall ® and its generic forms, directly to consumers using Internet advertisements and social media. Cerebral arranged for patients to receive prescriptions for ADHD treatments through a telehealth visit, and for Truepill to fill those prescriptions. In numerous instances, Truepill dispensed controlled substances pursuant to prescriptions that were not issued for a legitimate medical purpose in the usual course of professional practice. Many of these prescriptions were written by providers that lacked the requisite state certifications to prescribe and who issued multiple prescriptions for a patient to receive more than a 90-day supply of a

Schedule II controlled substance, including prescriptions for the treatment of ADHD, in violation of federal regulations.

Accordingly,

**PURSUANT** to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

**NOTICE** is hereby given to afford Truepill an opportunity to Show Cause before the Drug Enforcement Administration (DEA), at the DEA Hearing Facility, 700 Army Navy Drive, 2nd Floor, Arlington, Virginia 22202, or a location designated by the Administrative Law Judge, on March 21, 2023, or on such a subsequent date designated by the Administrative Law Judge (if Truepill requests such a hearing), as to why DEA should not revoke Truepill's DEA Certificate of Registration (COR or registration), Number FP6189725, pursuant to 21 U.S.C. § 824(a)(4), and deny any applications for any other DEA registrations, because Truepill's registration would be inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f).

As detailed below, this Order states DEA's basis to revoke the above-referenced DEA registration, including a ***non-exhaustive summary*** of the matters of fact and law at issue, as well as citations to laws and regulations that Truepill has violated (*see* 21 C.F.R. §§ 1301.36(e) and 1301.37(c), which DEA construes *in pari materia*). In order to preserve Truepill's rights in this proceeding, Truepill may appear in these revocation proceedings by filing a notice of appearance or request for hearing in the manner prescribed by regulations within 30 days from the receipt of this Order. On or before the date of Truepill's appearance, Truepill may submit a corrective action plan that will be considered by DEA in accordance with 21 U.S.C. § 824(c).

## LEGAL REQUIREMENTS

### Entities That Must Register as Online Pharmacies

Federal law proscribes any person from distributing or dispensing a controlled substance except as authorized by the Controlled Substances Act (CSA). *See* 21 U.S.C. §§ 841(a)(1); 842(a)(1). Federal law further explicitly provides that it is unlawful for "any person" to "deliver, distribute, or dispense a controlled substance by means of the Internet, except as authorized" by the CSA. 21 U.S.C. § 841(h)(1).

An "online pharmacy" is "a person, entity, or Internet site . . . that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet." 21 U.S.C. § 802(52)(A); *see also* 21 C.F.R. § 1300.04(h) (same). Further, the term "'deliver, distribute, or dispense by means of the Internet' refers, respectively, to any delivery, distribution, or dispensing of a controlled substance that is caused or facilitated by means of the Internet." 21 U.S.C. § 802(51). To act as an online pharmacy, a pharmacy must "request that the Administrator modify its registration to authorize the pharmacy to dispense controlled substances by means of the Internet as an online pharmacy." 21 C.F.R. § 1301.19(a); *see* 21 C.F.R. § 1301.11(b).

The CSA instructs that "it is unlawful for any person who falls within the [CSA's] definition of 'online pharmacy' . . . to deliver, distribute, or dispense a controlled substance by means of the

Internet" unless that person is "validly registered with a modification of such registration authorizing such activity." 21 C.F.R. § 1301.11(b). "Accordingly, any pharmacy registered" with DEA "that falls within the definition of an online pharmacy and proposes to dispense controlled substances by means of the Internet must obtain a modification of its registration authorizing such activity." *Id.*; *see also* 21 C.F.R. § 1301.19(f) ("No person . . . required to obtain a modification of a registration . . . authorizing it to operate as an online pharmacy may engage in any activity for which such modification of registration is required until the application for such modified registration is granted and an active Certificate of Registration indicating the modification of the registration has been issued by the Administrator to such person."). The CSA explicitly provides that "delivering, distributing, or dispensing a controlled substance by means of the Internet by an online pharmacy that is not validly registered with a modification authorizing such activity" is a violation of section 841(h)(1). 21 U.S.C. § 841(h)(2)(A).

Requirements Applicable to Online Pharmacies

An online pharmacy is subject to a number of requirements under the CSA. Among other things, an online pharmacy must:

- "[D]isplay in a visible and clear manner on its homepage a statement that it complies with the requirements of this section with respect to the delivery or sale or offer for sale of controlled substances." 21 U.S.C. § 831(a); 21 C.F.R. § 1304.45(a); *see also* 21 U.S.C. § 802(53) ("The term 'homepage' means the opening or main page or screen of the website of an online pharmacy that is viewable on the Internet.").

- Post "in a visible and clear manner" on its homepage or a page clearly linked from its homepage, the following information:

    - "The name, professional degree, and States of licensure of the pharmacist-in-charge, and a telephone number at which the pharmacist-in-charge can be contacted."

    - "A list of the States in which the pharmacy is licensed to dispense controlled substances."

    - "A certification that the pharmacy is registered under" the CSA "to deliver, distribute, or dispense" controlled substances "by means of the Internet."

    - The following statement: "This online pharmacy is obligated to comply fully with the Controlled Substances Act and DEA regulations. As part of this obligation, this online pharmacy has obtained a modified DEA registration authorizing it to operate as an online pharmacy. In addition, this online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation in accordance with section 309 of the Controlled Substances Act (21 U.S.C. 829) or a medical evaluation via telemedicine in

accordance with section 102(54) of the Controlled Substances Act (21 U.S.C. 802(54))."

*See* 21 U.S.C. § 831(c); 21 C.F.R. § 1304.45.

- Notify the DEA Administrator, thirty days before offering a controlled substance for sale, delivery, distribution, or dispensing, of, among other things: the information the online pharmacy is required to post on its Internet site under 21 U.S.C. § 831(c), and 21 C.F.R. § 1304.45; each Internet site address used by the online pharmacy; the DEA registration numbers of every pharmacy that delivers, distributes or dispenses controlled substances pursuant to orders made through each of those identified websites; and a certification that the information provided on its Internet site under 21 U.S.C. § 831(c), and 21 C.F.R. § 1304.45 is true and accurate. *See* 21 U.S.C. § 831(d); 21 C.F.R. § 1304.40(b).

- Display on its homepage a declaration that it has made an appropriate notification to the DEA Administrator. *See* 21 U.S.C. § 831(e); 21 C.F.R. § 1304.40(d).

- Monthly report to the DEA Administrator of the total quantity of controlled substances the online pharmacy has dispensed for each calendar month in which it dispenses either 100 or more controlled substance prescriptions, or 5,000 or more dosage units of controlled substances. If the pharmacy's dispensing does not meet either threshold in a given month, it must report a negative response for that month. *See* 21 C.F.R. § 1304.55.

Requirements Applicable to All Pharmacies

A "prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice." 21 C.F.R. § 1306.06. A pharmacist is only permitted to fill prescriptions "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). Although "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, . . . a corresponding responsibility rests with the pharmacist who fills the prescription." *Id.*

"DEA has consistently interpreted this provision as prohibiting a pharmacist from filling a prescription for a controlled substance when [s]he either knows or has reason to know that the prescription was not written for a legitimate medical purpose." *Wheatland Pharmacy*, 78 Fed. Reg. 69,441, 69,445 (2013) (internal quotation marks and citation omitted, alternation in original). Section 1306.04(a) "expressly requires pharmacists to identify and resolve suspicions that a prescription is illegitimate." *Trinity Pharmacy II*, 83 Fed. Reg. 7304, 7331 (2018).

A violation of these regulations is a violation of federal law. *See* 21 U.S.C. § 842(a)(1) (making it unlawful to dispense controlled substances in violation of 21 U.S.C. § 829, whose scope is defined in part by 21 C.F.R. §§ 1306.04, 1306.06). Any attempt to violate these regulations is also a violation of federal law. *See* 21 U.S.C. § 846.

Additionally, DEA may find that a registrant's DEA COR is inconsistent with the public interest if the registrant acted carelessly or negligently in handling controlled substances, even if the registrant did not intend to violate the Controlled Substances Act. *See, e.g.*, *Med. Shoppe*, 79 Fed. Reg. 59,504, 59,506 (2014) ("Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify revocation or denial." (quoting *Paul J. Caragine, Jr.*, 63 Fed. Reg. 51,592, 51,601 (1998))).

Pharmacies are also required to keep appropriate records as set forth in the CSA. "Recordkeeping is one of the CSA's principal tools for preventing the diversion of controlled substances." *Wayne Pharmacy*, 85 Fed. Reg. 63,579, 63,582 (2020). Such recordkeeping is one of the central features of the CSA's regulatory regime because "a registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances." *Superior Pharmacy I & Superior Pharmacy II*, 81 Fed. Reg. 31,310, 31,337 (2016). Thus, a finding that a registrant "failed to maintain complete and accurate records . . . supports the conclusion that [the registrant] has committed such acts as to render its continued registration 'inconsistent with the public interest.'" *Id.* at 31,338 (quoting 21 U.S.C. § 824(a)(4)).

Pharmacies are also required to, among other things, "maintain, on a current basis, a complete and accurate record of each [controlled] substance . . . received, sold, delivered, or otherwise disposed of." 21 U.S.C. § 827(a)(3); 21 C.F.R. § 1304.21(a); *see also* 21 C.F.R. § 1304.22(c) (specific recordkeeping requirements for dispensers).

An individual practitioner is not authorized, on a single occasion, to issue multiple prescriptions for a patient to receive more than a 90-day supply of a Schedule II controlled substance. *See* 21 C.F.R. § 1306.12(b).

State of California Authority to Dispense Controlled Substances

As noted above, a pharmacy may only fill valid prescriptions. *See* 21 U.S.C. § 829; 21 C.F.R. § 1306.06.

California law provides that to practice as a nurse practitioner in California, a nurse practitioner must hold, among other things, a valid and active registered nursing license issued by the Board of Registered Nursing (Nursing Board). Cal. Bus. & Prof. Code § 2835.5. Additionally, for a nurse practitioner licensed in California to prescribe a controlled substance, the Nursing Board must certify that the nurse practitioner satisfactorily completed a course in pharmacology covering the controlled substances to be prescribed and must issue a Furnishing Number to the nurse practitioner. *See id.* §§ 2836.1(g)(1), 2836.2, 2836.3.

To practice as a doctor of naturopathic medicine in California, one must hold a valid and active naturopathic medicine license issued by the California Naturopathic Medicine Committee. *See* Cal. Bus. & Prof. Code §§ 3630, 3633, 3644(d)(2). Schedule III through V controlled substances may only be dispensed by a naturopathic doctor under supervision by a physician or surgeon and pursuant to standardized procedures or protocols established between them. *See* Cal. Bus. & Prof. Code § 3640.5(f).

To practice as a physician assistant in California, one must hold a valid physician assistant license issued by the California Physician Assistant Board. *See* Cal. Bus. & Prof. Code § 3519;

*see also* Cal. Bus. & Prof. Code §§ 3501, 3503, 3516. Schedule II through V controlled substances may only be prescribed by a physician assistant under supervision by a physician or surgeon and pursuant to a practice agreement. *See* Cal. Bus. & Prof. Code §§ 3502.1 and 3516.

Additionally, practitioners licensed outside California may only be authorized to practice within California by the California Director of Emergency Medical Services Authority during a gubernatorially declared state of emergency. *See* Cal. Bus. and Prof. Code § 900.

**BACKGROUND**

1. Truepill is registered as a retail pharmacy under DEA COR Number FP6189725 in Schedules II through V with a registered address of 3121 Diablo Avenue, Hayward, California 94545. Truepill's registration expires by its own terms on November 30, 2025.

2. Truepill is not registered as an online pharmacy with DEA.

3. Truepill is licensed by the State of California as a community pharmacy with license number PHY58585. Truepill's pharmacy license expires by its own terms on March 1, 2023.

4. Between on or about September 14, 2020, and September 13, 2022, of the more than 72,000 controlled substances Truepill filled, nearly 46,000 were stimulants, accounting for more than 60% of the controlled substances Truepill dispensed.

5. Truepill's DEA COR should be revoked, and any applications for registration should be denied, because Truepill has committed such acts as would render its registration inconsistent with the public interest. *See* 21 U.S.C. §§ 823(f), 824(a)(4). Specifically, Truepill has acted as an online pharmacy without obtaining an appropriate DEA registration and without meeting a number of legal requirements applicable to online pharmacies. Truepill has, on numerous occasions, unlawfully filled controlled stimulant prescriptions issued by prescribers with no state authority to issue such prescriptions. Truepill has also repeatedly filled controlled stimulant prescriptions there were for more than a 90-day supply, in violation of 21 C.F.R. § 1306.12(b).

6. Dextroamphetamine-amphetamine, which is often sold under the brand names Adderall® and Adderall XR®, is a Schedule II stimulant.

7. Methylphenidate, which is often sold under the brand name Ritalin®, is a Schedule II stimulant.

**OPERATING AS AN ONLINE PHARMACY WITHOUT DEA REGISTRATION**

8. Truepill provides both pharmacy and technical services to corporate customers, including telehealth companies such as Cerebral. Moreover, Truepill employs a number of customer service representatives to assist its corporate customers.

9. On its Internet site, Truepill describes itself as a "virtual pharmacy," providing "[a]n end-to-end virtual pharmacy experience." Furthermore, Truepill claims that "Truepill's virtual pharmacy enables you to create the convenient experience your customers want."

10. Truepill provides its corporate customers with a software platform containing, among other things, patient information, prescriber information, and prescription information to facilitate the delivery of prescriptions by means of the Internet.

11. Truepill's Internet site also extensively describes how its software programs assist its corporate customers in providing patients with prescriptions. Among other things, the Truepill's Internet site includes the following statements:

    a. Truepill states that it can help companies "[d]eliver medications to your patients using powerful programmatic APIs [Application Programing Interfaces] that give you full control." It further states that these companies can "[p]air our pharmacy fulfillment services with our telehealth solutions to make your programs more accessible to patients who may find it difficult to commute to a doctor's office."

    b. Truepill informs that it provides other software that uses the Internet to facilitate the filling of prescriptions, including, among others, telehealth APIs to help practitioners create and update patient records, and to provide the practitioners' patients with patient health questionnaires, all in "the Truepill ecosystem." Truepill makes clear that its telehealth API customers are "third-party provider networks and physician groups that that can diagnose, treat and prescribe for your patient population. These providers are all part of licensed professional medical corporations who are independently owned and operated."

    c. Truepill explains that it uses a "fulfillment API" to assist providers to "efficiently get medications to your patient's door across all 50 states." Truepill goes on to explain how its software platform uses the Internet to electronically create patient records, obtain prescriptions, and allow practitioners to create fill requests that they submit to Truepill electronically.

    d. Truepill states that it offers a "team of marketers, merchandisers, and fulfillment experts" to help telehealth companies "maximize the value of your e-commerce program."

12. Through these services, Truepill "deliver[ed], distribute[ed], or dispense[ed]" "a controlled substance by means of the Internet," despite not being registered as an online pharmacy, in violation of 21 U.S.C. § 841(h)(1) and 21 C.F.R. §§ 1301.11(b) & 1301.19(f).

**FAILURE TO MAKE AND DISPLAY REQUIRED REPORTS AND NOTIFICATIONS**

13. Despite operating as an online pharmacy, Truepill failed to put on its Internet site information required by the CSA, including:

a. A statement on its homepage that Truepill complies with the requirements of 21 U.S.C. § 831 with respect to the delivery or sale or offer for sale of controlled substances, in violation of 21 U.S.C. § 831(a) and 21 C.F.R. § 1304.45(a).

b. A visible and clear statement on its homepage, or a page clearly linked from its homepage including:

   i. the name, professional degree, and states of licensure of its pharmacist-in-charge;

   ii. a telephone number at which its pharmacist-in-charge can be contacted;

   iii. a list of states in which Truepill is licensed to dispense controlled substances;

   iv. a certification that Truepill is licensed under the CSA to deliver, distribute, or dispense controlled substances by means of the Internet; and

   v. the following statement: "This online pharmacy is obligated to comply fully with the Controlled Substances Act and DEA regulations. As part of this obligation, this online pharmacy has obtained a modified DEA registration authorizing it to operate as an online pharmacy. In addition, this online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation in accordance with section 309 of the Controlled Substances Act (21 U.S.C. 829) or a medical evaluation via telemedicine in accordance with section 102(54) of the Controlled Substances Act (21 U.S.C. 802(54)).";

all in violation of 21 U.S.C. § 831(c) and 21 C.F.R. § 1304.45.

14. Truepill failed to notify the DEA Administrator of the information listed in 13.b., *supra*, through the submission of an application for a modified registration thirty days before offering a controlled substance for sale, delivery, distribution, or dispensing together with a certification that such information is true and accurate, in violation of 21 U.S.C. § 831(d) and 21 C.F.R § 1304.40(a)(1). Truepill also did not notify the DEA Administrator of each Internet site address it used, nor of the DEA registration numbers of every pharmacy that delivers, distributes or dispenses controlled substances pursuant to orders made through each of those identified websites, in violation of 21 U.S.C. § 831(d) and 21 C.F.R. § 1304.40(b)(3) and (4).

15. Truepill failed to display on the homepage of its Internet site that it had made an appropriate notification to the DEA Administrator under 21 U.S.C. § 831(d) and 21 C.F.R. § 1304.40(b), in violation of 21 U.S.C. § 831(e) and 21 C.F.R. § 1304.40(d).

16. Truepill failed to the provide the DEA Administrator with any of the monthly reports required by 21 C.F.R. § 1304.55.

**UNLAWFUL DISPENSING OF SCHEDULE II CONTROLLED SUBSTANCES PURSUANT TO PRESCRIPTIONS FOR GREATER THAN 90-DAY SUPPLY**

17. Between on or about September 13, 2020, and September 13, 2022, in dozens of instances, Truepill dispensed Schedule II controlled substances for prescriptions written on a single date by an individual practitioner to an individual patient for a greater than 90-day supply. A non-exhaustive set of examples is provided below.

18. On August 24, 2020, a practitioner issued **Patient N.S.** five prescriptions amounting to a 150-day supply of dextroamphetamine-amphetamine extended release (ER) 10 mg capsules, which are often sold under the brand name Adderall XR®, a total of 300 capsules, which Truepill dispensed.

19. On January 12, 2021, a practitioner issued **Patient L.H.** four prescriptions amounting to a 120-day supply of methylphenidate 20 mg tablets, which are often sold under the brand name Ritalin®, a total of 120 tablets, which Truepill dispensed.

20. On January 12, 2021, a practitioner issued **Patient L.H.** four prescriptions amounting to a 120-day supply of methylphenidate ER 54 mg tablets, which are often sold under the brand name Ritalin®, a total of 120 tablets, which Truepill dispensed.

21. On February 11, 2021, a practitioner issued **Patient D.K.** two prescriptions amounting to a 120-day supply of dextroamphetamine-amphetamine 20 mg tablets, which are often sold under the brand name Adderall®, a total of 120 tablets, which Truepill dispensed.

22. On February 11, 2021, a practitioner issued **Patient D.K.** two prescriptions amounting to a 180-day supply of dextroamphetamine-amphetamine ER 30 mg capsules, which are often sold under the brand name Adderall XR®, a total of 180 capsules, which Truepill dispensed.

23. On March 9, 2021, a practitioner issued **Patient H.M.** three prescriptions amounting to a 210-day supply of dextroamphetamine-amphetamine 10 mg tablets, which are often sold under the brand name Adderall®, a total of 315 tablets, which Truepill dispensed.

24. On November 8, 2021, a practitioner issued **Patient N.B.** four prescriptions amounting to a 120-day supply of dextroamphetamine-amphetamine ER 15 mg capsules, which are often sold under the brand name Adderall XR®, a total of 120 capsules, which Truepill dispensed.

25. On November 8, 2021, a practitioner issued **Patient N.B.** four prescriptions amounting to a 120-day supply of dextroamphetamine-amphetamine 5 mg tablets, which are often sold under the brand name Adderall®, a total of 120 tablets, which Truepill dispensed.

**UNLAWFUL DISPENSING OF CONTROLLED SUBSTANCES PURSUANT TO PRESCRIPTIONS ISSUED BY PRACTITIONERS WITHOUT STATE AUTHORITY**

26. Between on or about September 13, 2020, and September 13, 2022, Truepill dispensed controlled substances to patients located in California pursuant to prescriptions written by numerous practitioners who were neither sufficiently licensed in California to do so nor holders of an Authorization for Out-of-State Health Care Practitioner issued by the California Emergency Medical Services Authority (Temporary Emergency Authorization). These practitioners included nurse practitioners, physician assistants, and doctors of naturopathic medicine.

27. A non-exhaustive set of insufficiently licensed practitioners who also did not hold a Temporary Emergency Authorization include: **Nurse Practitioner N.B.**; **Nurse Practitioner T.C.**; **Nurse Practitioner D.S.**; **Nurse Practitioner H.M.**; **Nurse Practitioner J.M.**; **Nurse Practitioner A.N.**; **Nurse Practitioner S.O.**; **Nurse Practitioner A.S.**; and **Nurse Practitioner N.S.**

**RECORDKEEPING AND AUDIT FINDINGS**

28. In September and October of 2022, DEA investigators conducted an audit of Truepill's controlled substance records by conducting an inventory of certain controlled substances present at Truepill's registered location and comparing that inventory to the records maintained and provided by Truepill. DEA's audit identified 1,674 missing dosage units of dextroamphetamine-amphetamine ER 20 mg, often sold under the brand name Adderall XR®, for which Truepill was unable to account, in violation of 21 C.F.R. §§ 1304.21(a) and 1304.22(c). *See Bill Lloyd Drug*, 64 Fed. Reg. 1,823, 1,824 (1999) ("The shortages and overages revealed by the accountability audit show that Respondent does not keep complete and accurate records of its controlled substance handling as required by 21 U.S.C. 827 and 21 CFR 1304.21.").

29. This shortage of 1,674 units constituted over two percent of the dextroamphetamine-amphetamine ER 20 mg, often sold under the brand name Adderall XR®, for which Truepill was accountable during the audit period. Truepill's failure to account for a significant number of dosage units of controlled substances not only violated its obligation to maintain accurate records, but also constituted a failure to comply with its obligation to maintain effective controls against the diversion of controlled substances into illicit channels. *See, e.g.*, *Superior Pharmacy*, 81 Fed. Reg. at 31,337.

**THE** following procedures are available to Truepill in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause, Truepill may file with DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. *See* 21 C.F.R. § 1301.43(a). If Truepill fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause, Truepill may file with DEA a waiver of hearing together with a written statement regarding its position on the matters of fact and law involved. *See* 21 C.F.R. § 1301.43(c).

3. Should Truepill decline to file a request for a hearing, or should Truepill request a hearing and then fail to appear at the designated hearing, Truepill shall be deemed to

have waived the right to a hearing, and DEA may cancel such hearing and may enter a final order in this matter without a hearing based upon the evidence presented. *See* 21 C.F.R. §§ 1301.43(d), 1301.43(e).

Requests for hearing should be filed by email with the Office of Administrative Law Judges at the following address: ECF-DEA@dea.gov, with a copy simultaneously provided to the Government at the following address: DEA.Registration.Litigation@dea.gov. Except as provided below with respect to a corrective action plan, correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152. A copy of the same shall also be served on Government counsel, Edward O. Siclari, and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation Section, 8701 Morrissette Drive, Springfield, VA 22152. Matters are deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45.

**OPPORTUNITY TO SUBMIT CORRECTIVE ACTION PLAN**

In addition to the procedural options set forth in paragraphs 1 and 2 above, in accordance with 21 U.S.C. § 824(c)(2)(C), Truepill has the opportunity to submit a corrective action plan, which must be received by the Acting Assistant Administrator, Diversion Control Division, on or before the date of its appearance. Truepill is not required to submit a corrective action plan, nor will any adverse inference be drawn if Truepill chooses not to do so. If Truepill wishes to submit a corrective action plan, it must be submitted directly to the Acting Assistant Administrator, Diversion Control Division, who will decide whether, in view of the plan and the allegations set forth in this Order to Show Cause, the proceedings to revoke Truepill's registration should be discontinued, or deferred for the purposes of modification, amendment, or clarification of such plan. Any corrective action plan should be clearly labeled "Corrective Action Plan" and submitted by email to Thomas W. Prevoznik, Acting Assistant Administrator, Diversion Control Division, at the following address: CAPresponse@usdoj.gov.

A copy of the corrective action plan shall also be served on Government counsel, Edward O. Siclari, and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation Section, 8701 Morrissette Drive, Springfield, VA 22152.

In the event Truepill submits a corrective action plan and the Acting Assistant Administrator decides not to discontinue or postpone the proceedings, please note that such a decision is not a final determination by the agency regarding Truepill's corrective action plan or registration. In such circumstances, the Administrator may nonetheless consider the corrective action plan in issuing the final order at the conclusion of the proceedings.

Finally, please be advised that the submission of a corrective action plan shall not constitute a request for a hearing under paragraph 1 above or a written statement regarding Truepill's position on the matters of fact and law involved under paragraph 2 above. As indicated, if Truepill chooses to submit a corrective action plan and also wishes to proceed under paragraph 1 or 2 above, it must separately submit its request for a hearing (paragraph 1) or written statement (paragraph 2) in accordance with the instructions above.

THOMAS PREVOZNIK Digitally signed by THOMAS PREVOZNIK Date: 2022.12.15 17:15:08 -05'00'

Thomas W. Prevoznik
Acting Assistant Administrator
Diversion Control Division
Drug Enforcement Administration

cc: Hearing Clerk, Office of Administrative Law Judges
Edward O. Siclari, Counsel for the Government

BEFORE THE KANSAS BOARD OF PHARMACY

| | | |
|---|---|---|
| In the Matter of | ) | |
| | ) | Case No. 22-183 |
| PostMeds, Inc dba Truepill | ) | |
| | ) | |
| Registration No. 22-117859 | ) | |

**AMENDED SUMMARY ORDER**

NOW on this 20th day of January, 2023, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Director, the matter of PostMeds, Inc dba Truepill ("Respondent").

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board's Executive Secretary enters this Amended Summary Order in the above-captioned matter. After reviewing the investigation materials and being otherwise duly advised in the premises, makes the following findings, conclusions and order:

FINDINGS OF FACT

1. The Board has previously issued Respondent Registration No. 22-104228 which entitled Respondent to operate as a non-resident pharmacy in the State of Kansas.

2. On November 6, 2019, the ownership of Respondent's non-resident pharmacy changed.

3. On May 22, 2020, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 3, 2020 with an expiration date of June 30, 2021. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?"

Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

4. On June 1, 2021, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 21, 2021 with an expiration date of June 30, 2022. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?" Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

5. Due to staffing challenges, personnel turnover and administrative oversight resulting from its early, rapid growth and restructuring and the corresponding COVID-19 pandemic, Respondent mistakenly failed to report the 2019 ownership change and related disclosures to the Board in its May 22, 2020 and June 1, 2021 renewal applications.

6. On April 18, 2022, the Board received notification from Respondent of an ownership change and several past disciplinary actions not previously reported to the Board including: North Carolina Board of Pharmacy Consent Order of Discipline dated March 8, 2022; California State Board of Pharmacy Letter of Admonishment dated January 23, 2020; California State Board of Pharmacy Citation and Fine dated June 16, 2020; California State Board of Pharmacy Citation and Fine Order of Abatement dated August 25, 2021; Alabama State Board of Pharmacy Final Order dated October 25, 2021; California State Board of Pharmacy Citation and Fine dated January 24, 2019; and California State Board of Pharmacy Citation dated December 16, 2019.

7. On April 28, 2022, the Board received from Respondent a Form BA-22 Non-Resident Pharmacy Registration Application ("Respondent's Application"), notifying of the change in ownership effective November 6, 2019, and applying for a new non-resident pharmacy registration under the new ownership.

8. On May 20, 2022, the Board approved Respondent's Application and issued Respondent the new Non-Resident Pharmacy Registration No. of 22-117859 ("Respondent's Registration") under their new ownership.

9. Prior to receiving the ownership change application, registrant provided a letter notifying of the late ownership change, as well as unreported discipline. Ownership change application completed indicating discipline had occurred and providing details of discipline (5 occurrences).

10. In mitigation, Respondent states that it has invested in additional staff, engaged internal and external legal counsel and implemented training efforts to prevent any such reporting oversights in the future.

## CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f), the Board may take action against a registration on any ground that would authorize the board to take action against the registration of a pharmacy under K.S.A. 65-1627, and amendments thereto.

3. Pursuant to K.S.A. 65-1627(e)(1), the Board may take action against the registration of a pharmacy upon a finding that such pharmacy has been operated in such manner

that violations of the provisions of the pharmacy act of the state of Kansas or of the rules and regulations of the board have occurred in connection therewith.

4. Pursuant to K.S.A. 65-1627(e)(4), the Board may take action against the registration of a pharmacy upon a finding that the registrant has had a registration revoked, suspended or limited, has been censured or has had other disciplinary action taken, or an application for registration denied, by the proper registering authority of another state, territory, District of Columbia or other country.

5. Pursuant to K.S.A. 65-1657, no nonresident pharmacy shall ship, mail, or deliver, in any manner, prescription drugs to a patient in this state unless registered with the Board as a nonresident pharmacy.

6. Pursuant to K.S.A. 65-1645(f), registrations shall not be transferable.

7. Pursuant to K.A.R. 68-2-9, each registrant shall notify the executive secretary of the Board in writing of any change in majority ownership of the operation for which the registration was issued within five days after the date the change in ownership becomes effective.

8. Pursuant to K.A.R. 68-2-23, each pharmacy owner shall notify the board in writing within 30 days of any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by the state of Kansas or another jurisdiction against the pharmacy or the pharmacy owner or any application, license, registration, or permit held by the pharmacy owner.

9. Respondent's registered facility changed ownership on November 6, 2019 but Respondent did not provide notification or file a new application with the Board until April 18 and 28, 2022, respectively.

10. Respondent's failure to submit the complete change of ownership to the Board until April 2022 is a violation pursuant to K.A.R. 68-2-9 and an unlawful transfer of the previous

registration to the new ownership. Respondent's actions are a violation pursuant to K.S.A. 65-1657 and K.S.A. 65-1627(e)(1), and a basis to take action against Respondent's Registration.

11. Respondent failed to notify the Board of the six disciplinary actions by North Carolina, California, and Alabama until April 18, 2022, nearly one to two years after they were effective, is a violation of K.A.R. 68-2-23 and a basis to take action against Respondent's Registration pursuant to K.S.A. 65-1627(e)(1) and (e)(4).

## ORDER

Taking into account the mitigating and corrective actions of Respondent, the Board finds and concludes that Respondent's conduct, as described above, violates the Act and such conduct warrants the imposition of a fine pursuant to K.S.A. 65-1658, in the amount of $3,500.00. Respondent has 30 days from the date of this order to pay the fine.

## NOTICES

The Respondent is hereby notified as follows:

1. The Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231 within fifteen (15) days after service of this order.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within fifteen (15) days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to said statute. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

1/20/2023
Date

Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 24th day of January, 2023, deposit in business mail a copy of the foregoing Amended Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

PostMeds, Inc dba Truepill
3121 Diablo Ave
Hayward, CA 94545

and via email to:

Christopher C. Tillery
Seigfreid Bingham, P.C.
ctillery@sb-kc.com
Attorney for Respondent

/s/ Brenda L. Head
Brenda L. Head
Disciplinary Counsel for the Kansas Board of Pharmacy

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/13/2022)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of Pharmacy/MDEG/Wholesaler: Seven Hills Pharmacy LLC

Pharmacy/MDEG/Wholesaler License # (if applicable): N/A

Physical Address: 2722 E Kemper Rd

City: Sharonville State: OH Zip: 45241

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: Website:

Licensing Company Email:

**Section 2: Personal Information**

First: Mohammad Middle: Umar Last: Afridi

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: 5[redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Lavaca St PMB [redacted]

City: Austin State: TX Zip: 78701

Telephone: Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| University of Manchester UK | | 06/2005 | |
| **Address** | **City** | **State** | **Zip** |
| Oxford Rd | Manchester | UK | |
| **Diploma/Degree obtained, if any** | | | |
| Masters in Pharmacy | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 07/22-Current | Sorrento, Hawley Lane | Hale Barns, WA15 ODR | UK | |
| 12/21-7/22 | [redacted]La Canada Way | Bee Cave | TX | 78738 |
| 5/19-12/21 | [redacted]Elisha Lane | San Ramon | CA | 94583 |
| 1/18-5/19 | [redacted] True Wind Way Unit 607 | Redwood | CA | 94063 |
| 1/16-1/18 | [redacted] Willow Rd #202 | Pleasanton | CA | 94588 |
| 1/14-1/16 | [redacted] W San Carlos St 383 | San Jose | CA | 95126 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Truepill | | | 6/2016 - 8/2022 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 1700 S Amphlett Blvd | | San Mateo | CA | 94402 |
| **Phone** | **Title** | | | |
| 650-353-5495 | CEO | | | |

**Description of Duties**

Managed and directs the company toward goals and objectives, oversee executive business decisions

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| CVS | | | 12/2012 - 1/2016 | |
| **Business Address** | | **City** | **State** | **Zip** |
| Various Bay area locations | | San Jose | CA | |
| **Phone** | **Title** | | | |
| | Pharmacist | | | |

**Description of Duties**

Verified prescriptions for accuracy, patient consultations, supervise pharmacy technicians and clerks

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Rite Aid | | | 9/2010-7/2012 | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | Seattle | WA | |
| **Phone** | **Title** | | | |
| | Pharmacist | | | |

**Description of Duties**

Verified prescriptions for accuracy, patient consultations, supervise pharmacy technicians and clerks

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | | |
| | | | | |

**Description of Duties**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | | |
| | | | | |

**Description of Duties**

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | ✓ | |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | ✓ | |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | ✓ | |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | ✓ | |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # 4 & 6 . Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| 1/24/2019 | | CA | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| CI 2017 80030 | | California Board of Pharmacy | | |
| **Reason/Charge** | | | | |
| Failure to provide documentation substantiating completion of continuing education. Unprofessional conduct | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | **Lawsuit/Arbitration/Bankruptcy** | | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

CI 2017 80030 issued on January 24, 2019
Mr. Afridi received a citation and fine following an audit of the Continuing Education ("CE") requirements imposed on pharmacists by the State of California. California Board of Pharmacy alleges Mr. Afridi had not completed all CE requirements to maintain his California Registered Pharmacist license.

Mr. Afridi has paid the fine imposed by the California Board of Pharmacy. Upon receipt of the fine, the California Board of Pharmacy considered the matter closed and took no further action. Mr. Afridi's California Registered Pharmacist License remains active in good standing.

Mr. Afridi has since registered for the NABP CE Monitor tracking service, enabling him to remain compliant now and in the future.

M. U. Afridi
Original Signature (electronic, copies or stamps not accepted)

6/12/23
Date

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| 12/16/2019 | | CA | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| CI 2019 86472 | California Board of Pharmacy |

| Reason/Charge |
|---|
| furnished dangerous drugs on order of nurse practitioners who had not yet entered into an established protocol in place |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

CI 2019 86472 issued on December 16, 2019
Mr. Afridi received a citation while pharmacist-in-charge of Truepill PHY 56100. The California Board of Pharmacy alleges Truepill furnished dangerous drugs on order of nurse practitioners and physician assistants who had not yet entered into an established protocol in place.

M. U. Afridi
Original Signature (electronic, copies or stamps not accepted)

6/12/23
Date

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # 4 & 6. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| 10/25/2021 | | AL | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| 21-L-0080 | | Alabama Board of Pharmacy | | |
| **Reason/Charge** | | | | |
| Failure to timely notify the Alabama Board of Pharmacy of the California Board of Pharmacy Citation and Fine | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

21-L-0080 issued on October 25, 2021
Alabama Board of Pharmacy issued a Final Order to Mr. Mohammad Afridi, Alabama Registered Pharmacist #20384, regarding the California Board of Pharmacy Citation and Fine described below. Alabama Board of Pharmacy scheduled a reciprocal discipline hearing on the matter. The hearing was to discuss the California Board of Pharmacy Citation and Fine and to issue reciprocal discipline. Alabama Board of Pharmacy fined Mr. Afridi for failure to timely notify the Alabama Board of Pharmacy of the California Board of Pharmacy Citation and Fine. Mr. Afridi paid the fine to the Alabama Board of Pharmacy. Upon receipt of the fine, the Alabama Board of Pharmacy considered the matter closed and took no further action. Mr. Afridi's Alabama Registered Pharmacist License remains active in good standing.

M. U. Afridi
Original Signature (electronic, copies or stamps not accepted)

6/12/23
Date

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # 4 & 6 . Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| 03/07/2022 | | MI | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| 53-22-000152 | | Michigan Board of Pharmacy | | |
| **Reason/Charge** | | | | |
| Failure to timely notify the Michigan Board of Pharmacy of the California Board of Pharmacy Citation and Fine | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | **Lawsuit/Arbitration/Bankruptcy** | | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

53-22-000152 issued on 03/07/2022
Michigan Board of Pharmacy issued a consent Order to Mr. Mohammad Afridi, Michigan Registered Pharmacist #53-02-046254, regarding the California Board of Pharmacy Citation and Fine described below. Michigan Board of Pharmacy requested explanation of the California citation. Michigan Board of Pharmacy fined Mr. Afridi for failure to timely notify the Michigan Board of Pharmacy of the California Board of Pharmacy Citation and Fine. Mr. Afridi paid the fine to the Michigan Board of Pharmacy. Upon receipt of the fine, the Michigan Board of Pharmacy considered the matter closed and took no further action. Mr. Afridi's Michigan Registered Pharmacist License remains active in good standing.

Original Signature (electronic, copies or stamps not accepted)

6/12/23
Date

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # 5 . Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Mohammed Afridi does not have a direct ownership interest in any licensed pharmacy. Mr. Afridi does have an ownership interest in the grandparent level holding company of licensed pharmacies. In the interests of transparency the Postmeds, Inc (direct owner of Seven Hills Pharmacy, LLC) has been involved in discipline cases. Which are described in Postmeds Discipline summary (provided along with the original NV application).

MA

Original Signature (electronic, copies or stamps not accepted)

6/12/23

Date

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # 9. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

Mohammed Afridi does not have a direct ownership interest in any licensed pharmacy. Mr. Afridi does have an ownership interest in the grandparent level holding company of licensed pharmacies. In the interests of transparency the following pharmacies (also owned by Postmeds Inc) were voluntarily closed:

Lake Forest Pharmacy, LLC - closed on 6/23/22
Belle Isle Pharmacy, LLC - closed on 6/23/22
Wind City pharmacy, LLC - closed on 6/14/22
Queen City Pharmacy, LLC - closed on 8/17/2022

The following pharmacies have also closed since the initial submission of this application:
Overlake Pharmacy, LLC - closed on 03/15/23
LA Pharmacy, LLC - closed on 03/15/23
Marymoor Pharmacy, LLC - closed on 04/21/23
River City Pharmacy, LLC - closed on 04/14/23

M.U.A

Original Signature (electronic, copies or stamps not accepted)

6/12/23

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Mohammad Afridi

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/12/23

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

**Date**

Subscribed and Sworn to before me this _____ day of _____.

**Notary Public Signature**

**(Seal)**

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/13/2022)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of Pharmacy/MDEG/Wholesaler: Seven Hills Pharmacy, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable): OH 0232000312

Physical Address: 2722 E. Kemper Rd

City: Sharonville State: OH Zip: 45241

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 513-771-0367 Website: N/A

Licensing Company Email: compliance@truepill.com

**Section 2: Personal Information**

First: Siddharth Middle: Last: Viswanathan

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]Long Bridge Street, Apt [redacted]

City: San Francisco State: CA Zip: 94158

Telephone: [redacted] Email: compliance@truepill.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✔ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Carnegie Mellon University | | 09/2002-05/2006 | |
| **Address** | **City** | **State** | **Zip** |
| 5000 Forbes Avenue | Pittsburgh | PA | 15213 |
| Diploma/Degree obtained, if any | | | |
| Bachelor of Science Mechanical Engineering | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Watkins Mill High School | | 09/1998-05/2002 | |
| **Address** | **City** | **State** | **Zip** |
| 10301 Apple Ridge Road | Gaithersburg | MD | 20879 |
| Diploma/Degree obtained, if any | | | |
| High School Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 01/2021 - Present | [redacted] Long Bridge Street, Apt [redacted] | San Francisco | CA | 94158 |
| 02/2017 - 12/2020 | [redacted] Long bridge Street, Apt [redacted] | San Francisco | CA | 94158 |
| 09/2015 - 01/2017 | [redacted] King Street, Apt [redacted] | San Francisco | CA | 94107 |
| 11/2009 - 08/2015 | [redacted] Farrel Court | Mountain View | CA | 94043 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Truepill | | | 01/2016 - present |
| **Business Address** | **City** | **State** | **Zip** |
| 3100 Diablo Avenue | Hayward | CA | 94545 |
| **Phone** | **Title** | | |
| 855-910-8606 | CEO and Co-Founder | | |
| **Description of Duties** | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| LinkedIn | | | 01/2011 - 08/2014 |
| **Business Address** | **City** | **State** | **Zip** |
| 700 E. Middlefield Road | Mountain View | CA | 94043 |
| **Phone** | **Title** | | |
| 650-687-3600 | Product Manager | | |
| **Description of Duties** | | | |

Worked on CardMunch and other relationship management products for the world's largest professional network. Led the integration, relaunch, and growth of LinkedIn CardMunch, which was the most downloaded iPhone application for busines

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Cardmunch, Inc. (acquired by LinkedIn) | | | 11/2009 - 12/2010 |
| **Business Address** | **City** | **State** | **Zip** |
| 57 W El Camino Rea | Mountain View | CA | 94040 |
| **Phone** | **Title** | | |
| | Co-Founder | | |
| **Description of Duties** | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Johnson & Johnson | | | 07/2006 - 12/2008 |
| **Business Address** | **City** | **State** | **Zip** |
| One Johnson & Johnson Plaza | New Brusnwick | NJ | 08933 |
| **Phone** | **Title** | | |
| 732-524-0400 | Global Operations Leadership Development | | |
| **Description of Duties** | | | |

Part of a 2-year rotational program and held positions in the medical device (orthopedic implants, diabetic monitors) and pharmaceutical sectors. Key project involved the ramp-up a new$70M distribution facility for the pharmaceutical business

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✔ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Siddharth Viswanathan

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/10/2022

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of California, ss. County of San Francisco

I, Siddharth Viswanathan, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

10/13/2022

**Date**

Subscribed and Sworn to before me this 13th day of October, 2022

**Notary Public Signature**

JUDY ANN PARDINI
Notary Public - California
San Mateo County
Commission # 2329943
My Comm. Expires Jul 23, 2024

**(Seal)**

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/13/2022)

### Section 1: Pharmacy/MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Seven Hills Pharmacy, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable): OH 0232000312

Physical Address: 2722 E. Kemper Rd

City: Sharonville State: OH Zip: 45241

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 513-771-0367 Website: N/A

Licensing Company Email: compliance@truepill.com

### Section 2: Personal Information

First: Mathew Middle: Sloan Last: Davis-Ratner

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] 51st Ave S

City: Seattle State: WA Zip: 98118

Telephone: [redacted] Email: compliance@truepill.com

Are you a citizen of the United States? ■ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Columbia Law School | | | 2007-2010 | |
| Address | | City | State | Zip |
| 435 W 116th St | | New York | NY | 10027 |
| Diploma/Degree obtained, if any | | | | |
| J.D | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| Stanford University | | | 2002-2007 | |
| Address | | City | State | Zip |
| 450 Serra Mall | | Stanford | CA | 94305 |
| Diploma/Degree obtained, if any | | | | |
| M.A. and B.A. | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| Troy High School | | | 1998-2002 | |
| Address | | City | State | Zip |
| 2200 Dorothy Ln | | Fullerton | CA | 92831 |
| Diploma/Degree obtained, if any | | | | |
| High School Diploma | | | | |
| School Name | | | From - To (MM/YY – MM/YY) | |
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |
| School Name | | | From - To (MM/YY – MM/YY | |
| | | | | |
| Address | | City | State | Zip |
| | | | | |
| Diploma/Degree obtained, if any | | | | |
| | | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 12/2021 - present | [redacted]51st Ave S | Seattle | WA | 98118 |
| 3/2020 - 12/2021 | [redacted]Dahlia Pl | Corona del Mar | CA | 92625 |
| 12/2018 - 2/2020 | [redacted]44th Ave. | San Francisco | CA | 94122 |
| 1/2017 - 12/2018 | [redacted]Dahlia Pl | Corona del Mar | CA | 92625 |
| 8/2015 - 12/2017 | [redacted]Comerford Ln SE | Turner | OR | 97392 |
| 5/2011 - 8/2015 | [redacted]Dahlia Pl | Corona del Mar | CA | 92625 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Truepill, Inc | | | 3/2020-present |
| **Business Address** | **City** | **State** | **Zip** |
| 3121 Diablo Ave | Hayward | CA | 94545 |
| **Phone** | **Title** | | |
| 833-860-1057 | General Counsel | | |
| **Description of Duties** | | | |
| responsible for legal function of company | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Smith Health, Inc | | | 4/2019-3/2020 |
| **Business Address** | **City** | **State** | **Zip** |
| 300 Brannan St | San Francisco | CA | 94107 |
| **Phone** | **Title** | | |
| 8444540123 | Head of Legal and Corporate Operations | | |
| **Description of Duties** | | | |
| responsible for legal, compliance, people and facilities functions of company | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Incipio, LLC | | | 1/2017-8/2018 |
| **Business Address** | **City** | **State** | **Zip** |
| 3347 Michelson Dr STE 100 | Irvine | CA | 92612 |
| **Phone** | **Title** | | |
| 8007330088 | General Counsel & Secretary | | |
| **Description of Duties** | | | |
| responsible for legal function of company | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Kundalini Farms, LLC | | | 8/2015-12/2019 |
| **Business Address** | **City** | **State** | **Zip** |
| 14415 Comerford Ln SE | Turner | OR | 97392 |
| **Phone** | **Title** | | |
| n/a | Co-Founder | | |
| **Description of Duties** | | | |
| esponsible for operational functions of company | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Nextgen Healthcare, Inc | | | 7/2013-9/2015 |
| **Business Address** | **City** | **State** | **Zip** |
| 18111 Von Karman Ave Suite 600 | Irvine | CA | 92612 |
| **Phone** | **Title** | | |
| 9492552600 | Vice President, Associate General Counsel and Assistant Secretary | | |
| **Description of Duties** | | | |
| member of legal function of company | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Latham & Watkins LLP | | | 11/2010-7/2013 |
| **Business Address** | **City** | **State** | **Zip** |
| 650 Town Center Dr #20 | Costa Mesa | CA | 92626 |
| **Phone** | **Title** | | |
| 7145401235 | Associate | | |
| **Description of Duties** | | | |
| associate in legal services organization | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |
| | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| | | | |
| **Business Address** | **City** | **State** | **Zip** |
| | | | |
| **Phone** | **Title** | | |
| | | | |
| **Description of Duties** | | | |
| | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✔ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted) Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Mathew Davis-Ratner

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/28/22

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Washington, ss. County of King

I, Mathew Davis-Ratner, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

10/28/22

**Date**

Subscribed and Sworn to before me this 28 day of October 2022.

**Notary Public Signature**

GENNELL CLAUDETTE HUNTER
Notary Public
State of Washington
Commission # 203817
My Comm. Expires Oct 11, 2026

**(Seal)**

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

### Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Seven Hills Pharmacy, LLC

Pharmacy/Wholesaler License # (if applicable): 0232000312

Physical Address: 2722 E. Kemper Rd

City: Sharonville State: OH Zip: 45241

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 513-771-0367 Website:

Licensing Company Email: compliance@truepill.com

### Section 2: Personal Information

First: Christopher Middle: William Last: Spitzer

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Gardenside Lane

City: Loveland State: OH Zip: 45140

Telephone: Email: christopher.spitzer@truepill.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| University of Massachusetts, Dartmouth | | 09/16 - 05/18 | |
| **Address** | **City** | **State** | **Zip** |
| 285 Old Westport Rd | North Dartmouth | MA | 02747 |
| Diploma/Degree obtained, if any | | | |
| MBA | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| Massachusetts College of Pharmacy and Health Sciences | | 09/04 - 05/10 | |
| **Address** | **City** | **State** | **Zip** |
| 179 Longwood Ave | Boston | MA | 02115 |
| Diploma/Degree obtained, if any | | | |
| PharmD | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| Gateway Regional High School | | 09/00 - 06/04 | |
| **Address** | **City** | **State** | **Zip** |
| 12 Littleville Rd | Huntington | MA | 01050 |
| Diploma/Degree obtained, if any | | | |
| High School Diploma | | | |
| School Name | | From - To (MM/YY – MM/YY) | |
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |
| School Name | | From - To (MM/YY – MM/YY | |
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 03/18 - present | [redacted] Gardenside Ln | Loveland | OH | 45140 |
| 10/17 - 03/18 | [redacted] Sanctuary Ln | Maineville | OH | 45039 |
| 09/13 - 09/17 | [redacted] Winchester St | Brookline | MA | 02446 |
| 09/10 - 08/13 | [redacted] Island Hill Ave | Malden | MA | 02148 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Seven Hills Pharmacy | | | 09/21 - present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 2722 E. Kemper Rd | | Sharonville | OH | 45241 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| (513) 771-0367 | Pharmacist-in-Charge | | 2,200 | |
| **Description of Duties** | | | | |
| Managing all pharmacy operations, hiring pharmacy/warehouse personnel, filling/shipping prescriptions, inventory management | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| CVS Health | | | 1/18 - 8/21 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 13 Mary St | | Cincinnati | OH | 45216 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| (800) 746-7287 | District Leader, Pharmacy Supervisor, Pharmacy Manager | | 7,040 | |
| **Description of Duties** | | | | |
| Responsible for the overall retail store operations in assigned district (28 Stores), P&L management, operating COVID clinics, inventory management | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

**Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY**

Managing Pharmacist Name: Christopher Spitzer Pharmacist Registration #: 03236754

Pharmacy Name: Seven Hills Pharmacy, LLC

**Initial each statement below to indicate you have read and agree with the following:**

CS I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

CS I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

CS I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

CS I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

CS I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

| Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |
| 2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state? | | ✔ |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? | | ✔ |
| 4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state? | ✔ | |

**If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.**

| Board Administrative Action: | State: | Date: | Case #: |
|---|---|---|---|
| Written Reprimand and Penalty | Ohio | 3/9/2022 | A-2021-0336 |

| Criminal Action: | State: | Date: | Case #: | County: | Court: |
|---|---|---|---|---|---|
| N/A | | | | | |

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

12/7/22
Date

**Christopher W. Spitzer**
[redacted] Gardenside Ln
Loveland, OH 45140
[redacted]

September 9, 2022

**Nevada State Board of Pharmacy**
985 Damonte Ranch Pkwy, Ste. 206
Reno, NV 89521

To whom it may concern,

Attached please find the details concerning a recent settlement between myself and the Ohio Board of Pharmacy. The fine of $250 has already been paid and the additional CE hours (5) will be submitted by the end of the month.

If you need any more information from me feel free to reach out via phone/email at any time.

Sincerely,

Christopher W. Spitzer

RECEIVED
SEP 19 2022
NEVADA STATE BOARD
OF PHARMACY

STATE OF OHIO BOARD OF PHARMACY

IN THE MATTER OF:

CASE NO. A-2021-0336

Christopher Spitzer, RPh
[redacted] Gardenside Lane
Loveland, Ohio 45140

License No. 03-236754

## SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Christopher Spitzer, RPh, for the purpose of resolving all issues between the parties relating to the Board investigation of Christopher Spitzer and CVS Pharmacy #6123 for failing to report a pharmacist for arriving to work his scheduled shift at CVS Pharmacy while impaired and under the influence of alcohol. Together, the Board and Christopher Spitzer are referred to hereinafter as "the parties."

### JURISDICTION

1. Pursuant to Section 4729.16 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Sections 4729.07 and 4729.08 of the Ohio Revised Code to practice pharmacy in the state of Ohio.

2. Christopher Spitzer is a licensed pharmacist in the state of Ohio under license number 03-236754, who was listed as the District Manager at CVS Pharmacy #6123, located at 7500 Beechmont Avenue, Cincinnati, Ohio, at the time of the Allegations in the Notice of Opportunity for Hearing dated March 9, 2022.

### FACTS

1. The Board initiated an investigation of Christopher Spitzer, pharmacist license number 03-236754, and CVS Pharmacy #6123 for failing to report a pharmacist for arriving to work his scheduled shift at CVS Pharmacy while impaired and under the influence of alcohol.

2. On or about March 9, 2022, the Board sent a Notice of Opportunity for Hearing to Christopher Spitzer, which outlined the allegations and provided notice of his right to a hearing, his rights in such hearing, and his right to submit contentions in writing.

3. On or about March 31, 2022, Christopher Spitzer, timely requested an administrative hearing, which was subsequently scheduled for April 6, 2022. Settlement of this matter was reached prior to hearing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative proceedings.

**TERMS**

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Christopher Spitzer neither admits nor denies the allegations stated in the Notice of Opportunity for hearing letter dated March 9, 2022; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. Christopher Spitzer agrees to pay to the Board a monetary penalty in the amount of $250.00. This fine will be attached to Christopher Spitzer' license record and must be paid no later than 180 days from the effective date of this Order. To pay this fine, login to www.elicense.ohio.gov and process the items in the cart.

4. Christopher Spitzer must obtain five hours of approved continuing pharmacy education (0.5 CEUs) which may not also be used for license renewal. The 0.5 CEUs must be completed within six months from the effective date of this agreement. Copies of completed CEUs must be e-mailed to legal@pharmacy.ohio.gov.

5. The Board hereby imposes a written reprimand on Christopher Spitzer's pharmacist license, number 03-236754.

6. Christopher Spitzer agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. Christopher Spitzer understands that he has the right to be represented by counsel for review and execution of this agreement.

8. Christopher Spitzer agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction in which he currently holds a professional license, including to the Board on renewal applications or applications for a new license.

9. Christopher Spitzer explicitly withdraws his request for a hearing, waives an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code, and waives any right to an appeal.

10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

13. If any of the provisions, terms, or clauses of this Agreement are declared illegal, unenforceable, or ineffective by an authority of competent jurisdiction, those provisions, terms, and clauses shall be deemed severable, such that all other provisions, terms, and clauses of this Agreement shall remain valid and binding upon both Parties.

14. This Agreement shall become effective upon the date of the Board President's signature below.

*[SIGNATURE PAGE FOLLOWS]*

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

| | |
|---|---|
| Christopher Spitzer, RPh, Respondent | 7/20/22<br>Date of Signature |
| James J. Leo, Attorney for Respondent | 7/20/22<br>Date of Signature |
| Shawn Wilt, RPh, President,<br>State of Ohio Board of Pharmacy | 08.11.2022<br>Date of Signature |
| N/A<br>Henry Appel, Ohio Assistant Attorney General | N/A<br>Date of Signature |

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✔ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # _____. **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| Reason/Charge | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| Name of Business/Industry/Entity | | | | |

**Provide explanation below:**

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

**I,** Christopher Spitzer **, certify that as the designated representative for**

Seven Hills Pharmacy, LLC ,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. x I am at least 21 years of age;
3. X I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. X I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. X I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. X I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. X I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Christopher Spitzer

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/18/22

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Christopher Spitzer

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/18/22

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Ohio, ss. County of Hamilton

I, Christopher Spitzer, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

10/18/22

**Date**

Subscribed and Sworn to before me this 18th day of October 2022

**Notary Public Signature**

HAYLEY ABNEY - NOTARY PUBLIC
COMM EXP: AUG 4, 2025
STATE OF OHIO

**(Seal)**

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/13/2022)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of Pharmacy/MDEG/Wholesaler: Seven Hills Pharmacy, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable): OH 0232000312

Physical Address: 2722 E. Kemper Rd

City: Sharonville State: OH Zip: 45241

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 513-771-0367 Website: N/A

Licensing Company Email: compliance@truepill.com

**Section 2: Personal Information**

First: Daniel Middle: Yitzhak Last: Simkin

Alias(es, nicknames, name changes, etc.): Donny Simkin

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Hyperion Ave

City: Los Angeles State: CA Zip: 90029

Telephone: [redacted] Email: compliance@truepill.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✔ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Valley Torah High School | | 09/96 - 06/00 | |
| Address | City | State | Zip |
| 12517 Chandler Blvd | Valley Village | CA | 901607 |
| Diploma/Degree obtained, if any | | | |
| High School Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Stanford University | | 09/03 - 06/07 | |
| Address | City | State | Zip |
| 450 Serra Mall | Stanford | CA | 94305 |
| Diploma/Degree obtained, if any | | | |
| BA English | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| UCLA School of Law | | 08/13 - 05/16 | |
| Address | City | State | Zip |
| 385 Charles E Young Dr E | Los Angeles | CA | 90095 |
| Diploma/Degree obtained, if any | | | |
| JD | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 07/19 - Present | [redacted] Hyperion Ave | Los Angeles | CA | 90029 |
| 05/15 - 07/19 | [redacted] Lucile Ave # [redacted] | Los Angeles | CA | 90027 |
| 02/15 - 05/15 | 1[redacted] S Wooster St # [redacted] | Los Angeles | CA | 90035 |
| 04/14 - 02/15 | [redacted] Weyburn Ter [redacted] | Los Angeles | CA | 90024 |
| 10/12 - 04/14 | [redacted] Castle Heights Ave | Los Angeles | CA | 90034 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Truepill, Inc. | | | 08/21 - Present | |
| **Business Address** | **City** | | **State** | **Zip** |
| 3121 Diablo Ave | Hayward | | CA | 94545 |
| **Phone** | **Title** | | | |
| (855) 910-8606 | Associate General Counsel | | | |
| **Description of Duties** | | | | |
| Attorney | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Barta Tate | | | 04/18 - 03/20 | |
| **Business Address** | **City** | | **State** | **Zip** |
| 1801 Century Park E STE 1200 | Los Angeles | | CA 9006 | |
| **Phone** | **Title** | | | |
| (310) 479 - 1454 | Associate | | | |
| **Description of Duties** | | | | |
| Attorney | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Strook & Stroock & Lavan LLP | | | 09/16 - 12/17 | |
| **Business Address** | **City** | | **State** | **Zip** |
| 2029 Century Park E 18th Floor | Los Angeles | | CA | 90067 |
| **Phone** | **Title** | | | |
| (310) 556 - 5800 | Associate | | | |
| **Description of Duties** | | | | |
| Attorney | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Sparks Consulting | | | 08/12 - 09/13 | |
| **Business Address** | **City** | | **State** | **Zip** |
| Virtual | | | | |
| **Phone** | **Title** | | | |
| (214) 557 - 0111 | Senior Associate | | | |
| **Description of Duties** | | | | |
| Athletic and academic counseling | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | **City** | | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | ✔ | |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✔ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | ✔ | |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # 4 . Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| 12/25/2012 | N/A | CA | Los Angeles | Los Angeles |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| #3VY002301-01 | Superior Court of California |

| Reason/Charge |
|---|
| Driving under the influence of an alcoholic beverage |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| DANIEL YITZHAK SIMKIN | N/A |

| Name of Business/Industry/Entity |
|---|
| N/A |

**Provide explanation below:**

On January 29, 2013, Manager Daniel Simkin received a misdemeanor alcohol DUI conviction under California Vehicle Code section 23152(b). See Los Angeles Superior Court (2013), Case #3VY002301-01; see also Exhibit A, Misdemeanor Sentencing Memorandum – Vehicle Code. On March 22, 2016, this misdemeanor conviction was dismissed under California Penal Code section 1203.4. See Exhibit B, Order for Dismissal.
On January 11, 2018, Mr. Simkin was admitted to the State Bar of California and remains active and in good standing (State Bar Number: 319806).

Original Signature (electronic, copies or stamps not accepted)

10/28/22
Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Daniel Simkin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/28/22

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of California, ss. County of Los Angeles

I, Daniel Simkin, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

10/31/22

**Date**

Subscribed and Sworn to before me this 31st day of October 2022.

**Notary Public Signature**

KEITH McGRUDER
COMM# 2293123
Notary Public - California
Los Angeles County
My comm. Expires July 12, 2023

(Seal)

# Exhibit A

SUPERIOR COURT OF CALIFORNIA
COUNTY OF LOS ANGELES

THE PEOPLE OF THE STATE OF CALIFORNIA,
OR 01/15/2013 Bkg no. 3409911
Plaintiff,

vs.

DANIEL YITZHAK SIMKIN [redacted] M

V23152a/no prior

V23152b

Defendant(s).

MISDEMEANOR COMPLAINT

Case number: 3VY00230

FILED
JOHN A. CLARKE
Executive Officer/Clerk

By_____
Deputy Clerk

Issued by
CARMEN A. TRUTANICH
City Attorney

By_____
KATHLEEN FORD (LT)
Deputy City Attorney

Comes now the undersigned and states that he is informed and believes, and upon such information and belief declares: That on or about 12/25/2012 at and in the City of Los Angeles, in the County of Los Angeles, State of California, a misdemeanor, to wit, violation of Subdivision (a) of Section 23152 of the California Vehicle Code was committed by the above-named defendant(s) (whose true name(s) to affiant is(are) unknown), who at the time and place last aforesaid, did willfully and unlawfully drive a vehicle while being under the influence of an alcoholic beverage and a drug and under the combined influence of an alcoholic beverage and a drug.

MCI 23152(A)/29

COUNT II

For a further, separate and second cause of action being a different offense, belonging to the same class of crimes and offenses set forth in Count I hereof, affiant further alleges that on or about 12/25/2012 at and in the City of Los Angeles, in the County of Los Angeles, State of California, a misdemeanor, to wit, violation of Subdivision (b) of Section 23152 of the California Vehicle Code was committed by the above-named defendant(s) (whose true name(s) to affiant is(are) unknown), who at the time and place last aforesaid, did willfully and unlawfully drive a vehicle with 0.08 percent or more, by weight, of alcohol in his or her blood.

The allegations of prior convictions listed in Count I of this complaint are hereby incorporated by reference as allegations of prior convictions for the purposes of this Count of the complaint.

MCI 23152(B)/29

All of which is contrary to the law and against the peace and dignity of the People of the State of California. Declarant and complainant therefore prays that a warrant may be issued for the arrest of said defendant(s) and that he may be dealt with according to law.

Attached hereto and incorporated by reference as though fully set forth are written statements and reports which constitute the basis upon which I make the within allegations.

A declaration in Support of the Issuance of Such Warrant is Submitted.

Executed at Los Angeles, California, on

I declare under penalty of perjury that the foregoing is true and correct.

A. Martinez
Declarant and Complainant

INFORMAL DISCOVERY NOTICE

TO THE ABOVE-NAMED DEFENDANT(S) AND/OR ATTORNEY(S) FOR DEFENDANT(S):

Plaintiff, the People of the State of California, hereby requests discovery/disclosure from the defendant(s) and his or her attorney(s) in this case pursuant to Penal Code Sections 1054.3 and 1054.5.

YOU ARE HEREBY NOTIFIED that if complete disclosure is not made within 15 days of this request, plaintiff will seek -- on or before the next court date, or as soon as practicable thereafter -- a court order enforcing the provisions of Penal Code Section 1054.1, subdivisions (b) and (c). This is an ongoing request for any of the listed items which become known to the defendant(s) and his or her attorney(s) after the date of compliance.

The written statements and reports attached hereto constitute discoverable materials designated in Penal Code Section 1054.1. Any additional material discoverable pursuant to Penal Code Section 1054.1 that becomes known to plaintiff will be provided to the defense.

If, prior to or during trial, as a result of this request plaintiff obtains additional evidence or material subject to disclosure under a previous defense request or court order pursuant to Penal Code Section 1054.1, plaintiff will disclose the existence of that evidence or material within a reasonable time.

DISCOVERY MATERIALS SHOULD BE DELIVERED TO A DEPUTY CITY ATTORNEY IN TRIAL COURT ON THE FIRST TRIAL DATE.

Line Reference Target LRT-BE4-V3

# SUPERIOR COURT OF CALIFORNIA, COUNTY OF LOS ANGELES

## MISDEMEANOR SENTENCING MEMORANDUM - VEHICLE CODE

| | | | | | |
|---|---|---|---|---|---|
| Defendant: DANIEL Simlin | | | | Case No: 3VY00250 | |
| Date: | Dep't/Div.: 103 | Prosecutor: | | Defense: | |
| Judge: OMANS | Clerk: HARPOOK | Reporter: | | Interpreter/Language: | |

As to Count 1, a violation of Penal Code § [ ] 23152(a) [ ] 23152(b) [ ] 23103 per 23103.5 [ ] 14601 [ ] 12500(a) [ ] _____ with ___ admitted priors.

**Arraignment For Judgment**

[ ] Arraignment for judgment and time for sentencing waived. There is no legal cause why judgment should not now be pronounced.

**Sentence**

1. [ ] **Probation is denied.** Defendant is to serve _____ days/hours in the Los Angeles County Jail, forthwith, [ ] consecutive [ ] concurrent with _____. Defendant to receive total credit of _____ days/hours (credit _____ days/hours actual plus _____ days GT/WT).
2. [ ] Pay a fine of $ _____ plus all applicable penalty assessments and enhancements.
3. [ ] Pay all fines and assessments as set forth in Paragraph 20 below.
4. [ ] **Execution of the foregoing sentence is suspended, on the following terms and conditions.**

**Conditional Sentence (PC §1203b/Order of Probation (PC §1203a)**

[ ] **Imposition of sentence is suspended (ISS)** [ ] With supervision by county probation officer (formal probation)
For a period of 36 months upon the following terms and conditions:

1. [ ] **Serve _____ days/hours in the Los Angeles County jail,** [ ] consecutive [ ] concurrent with _____. Defendant to receive credit of _____ days/hours actual plus _____ days/hours GT/WT. [ ] Time may be served in any penal institution.
   [ ] Time may be served on consecutive weekends of two days each, beginning _____ **(772)**
   [ ] Time may be served in any city jail having actual confinement, at defendant's expense. **(021)**
   [ ] Defendant may not participate in Sheriff's home detention/EHM per PC 1203.016(e). **(771)** [ ] Work furlough / early release not allowed.
   [ ] Last _____ days of jail time to be served in: [ ] Antelope Valley Rehabilitation Center [ ] _____ Program. **(002)**
   Defendant to be released only to an authorized representative of that program and is to comply with all program terms and conditions. **(013)**
   If defendant leaves or is discharged from the program prior to completion, defendant is to report to court on the next court day. **(013)**
2. [ ] **Pay a fine of $ 390 plus penalty assessments or** in default thereof serve _____ additional days in County jail consecutive **or** perform _____ days of Community Labor/ _____ or perform _____ days/hours of approved Community Service with credit for _____ days actual or $_____ toward fine for jail time already served. [ ] Fine may be paid in monthly installments of $_____ **(124)** [ ] Defendant to report to Financial Evaluator to work out a payment plan.
   [ ] Defendant elects jail in lieu of fine, forthwith, consecutive to all other time, credit _____ days actual plus _____ days GT/WT.
3. [ ] Perform _____ days of work for Community Labor/ _____ or perform _____ days/hours of approved Community Service, with credit for _____ days actual. Sign up for all work or Community Service only at a court-approved volunteer center or in the clerk's office. Failure to complete court-ordered work or Community Service without excuse may result in jail. **This work or Community Service is in addition to that done in lieu of fine.**
4. [ ] Make **restitution to victim** _____ per PC §1202.4(f). **(048)** [ ] in an amount to be determined at a hearing. **(067)** [ ] *Harvey* waiver taken.
   [ ] in the stipulated sum of $_____. **(048)** [ ] per any final civil judgment against you. **(100)** [ ] Liability is admitted but amount is disputed.
5. [ ] **Enroll within 21 days (or within 21 days from your release from custody) and successfully complete an approved:** Defendant's BAC: _____ %. [ ] **Refusal**
   [ ] 12 hour (SB 1176) [ ] 3 mo. (AB541)**(327)** [ ] 6 mo. (AB 768) [ ] 9 mo. (AB1353) [ ] 18 mo. (SB38)**(328)** [ ] 30 mo. alcohol education program.
   The DMV will not restore your driving privilege until you successfully complete a licensed alcohol education program. [ ] Obtain program details Clerk or Health Officer.
6. [ ] Attend 16 Alcoholics Anonymous/Narcotics Anonymous meetings at the rate of ___ times per week, IN ADDITION to those required as part of the alcohol education program. **(246)**
7. [ ] **Do not drive any vehicle with any measurable amount of alcohol or drugs in your blood,** or refuse to take and complete any blood alcohol/drug chemical test, any field sobriety test or any preliminary alcohol screening test when requested by any peace officer. **(711)**
8. [ ] Do not drive a motor vehicle without a valid driver's license in your possession, or without liability insurance in at least the minimum amounts required b law. **(374)**
9. [ ] Abstain from the use of all alcoholic beverages and stay out of all places where they are a chief item of sale. **(300)**
10. [ ] Enroll in and complete the [ ] Hospital and Morgue ("HAM") Program. **(471)** [ ] MADD Victim Impact Program **(472)** [ ] _____
11. [ ] The court finds that defendant presents a traffic safety or public safety risk and, per VC §13352.4(d), disallows issuance by DMV of a restricted license. **(249)**
12. [ ] **Your driver's license is hereby ordered [ ] suspended [ ] revoked** for a period of ____ months ____ years. [ ] **"M" service given in open court. (283)**
    You may not drive a motor vehicle unless and until your driving privilege is restored. [ ] Defendant under age 21 at time of offense.
13. [ ] You are hereby declared to be a Habitual Traffic Offender for a period of _____ years. **(263)**
14. [ ] Comply with the "Supplemental Terms of Probation – Ignition Interlock Device" regarding installation of an ignition interlock. **(248)**
15. [ ] Do not own, use possess, buy or sell any controlled substances, or associated paraphernalia, except with valid prescription, and stay away from places where users, buyers or sellers congregate. Do not associate with persons known by you to be controlled substance users or sellers, except in an authorized drug counseling program. **(926)**
16. [ ] Submit your person and property to search and seizure at any time of the day or night, by any Probation Officer or other peace officer, with or without a warrant, probable cause or reasonable suspicion. **(576)**
17. [ ] The vehicle with license plate _____ is, after notice and hearing, ordered impounded for _____ days per Vehicle Code § 23594(a). **(703)**
18. [ ] The vehicle with license plate _____ is, after notice and hearing, ordered confiscated and sold per Vehicle Code § 23596(a).
19. [ ] If you are deported from or otherwise leave the United States, notify the Court [and Probation] in writing of your address and telephone number outside the United States within 72 hours of deportation or departure. Continue to pay all of your financial obligations to the Court [and to Probation] while outside the United States. **(474)**
20. [ ] **Pay all of the following (check all that apply):**

| | |
|---|---|
| [ ] **A restitution fine** of [ ] $100.00, [ ] $_____, per PC §1202.4(b) through (e). **(098)** | [ ] **An administrative screening fee** of $25 per PC 1463.07/GC §29550(f) (D released OR.) |
| [ ] **A probation revocation restitution fine** in the same amount as the restitution fine, per PC §1202.44, payment is stayed until probation is revoked and sentence imposed. | [ ] **A citation processing fee** of $10.00 per PC §1463.07 and GC §29550(f) (if D cited and released in field or at jail facility.) |
| [ ] **A criminal conviction/facilities assessment** of $30.00 per Gov't Code §70373(a). (SA:CC) | [ ] An alcohol abuse education and prevention penalty assessment of $_____ ($50 max.) per VC §23645 |
| [ ] **A criminal fine surcharge** of $_____ per Penal Code §1465.7 (20% of base fine). (SA:AB) | [ ] An alcohol and drug problem program assessment of $_____ ($100.00 max.) per VC §23649. |
| [ ] **A court security fee** of $20.00 per PC §1465.8(a)(1). (per count) (SA:SF) | [ ] A drug program fee of $150.00 (per drug count except §11357(b)) per H&S §11372.7(a). |
| [ ] **A criminal justice administration fee** of $_____, payable to the local arresting agency, per Gov't Code §§ 29550(c), 29550.1 or 29550.2 (agency's actual cost) | [ ] A crime lab fee of $50.00 plus penalty assessment per H&S Code §11372.5. **(184)** |
| [ ] **Cost of probation services** per PC 1203.1b, [ ] as determined by the Probation Officer, subject to a hearing if requested, in the amount of $_____ per month. | |

NOTIFY DMV OF ANY ADDRESS CHANGE WITHIN 10 DAYS

21. [ ] _____
22. [ ] **Obey all laws** and orders of the Court **(541)**, [ ] and rules and regulations of the Probation Department. **(542)**

[ ] **Defendant acknowledges that he/she understands and accepts the terms and conditions of probation. (810)**
[ ] Defendant ordered to pay attorney fees [ ] in the amount of $_____ [ ] in the amount determined by the Financial Evaluator.
[ ] **Counts/allegations** _____ **are dismissed/stricken** on the People's motion pursuant to Penal Code Section 1385 as to this defendant.

**Compliance Dates: Defendant is ordered to appear in person on each of the following compliance dates. (683)**

| | | | |
|---|---|---|---|
| Surrender for jail: [ ] *Cruz* waiver taken: | | Restitution Hearing in Div/Dep't _____ at 8.30 a.m. | |
| Pay fine/fees in full by: [ ] installments allowed | 1-29-14 c/s | POE/Proof of Completion of Alcohol Program: | 6-28-13 c/s |
| Complete jail/work/c-s by: | | Other: | |

**I understand, accept and will comply with the foregoing conditional sentence and compliance dates and will return to Court as ordered.**

| **Defendant's Signature:** | **Attorney's Signature Joining:** |
|---|---|

Defendant's Address: _____
Defendant's Telephone: _____

_____
Judge/Commissioner of the Superior Court

CRIM 088 (Rev. 5/1/09) DISTRIBUTION: Pink - Court Copy White - Defendant Copy

# Exhibit B

CR-181

| ATTORNEY OR PARTY WITHOUT ATTORNEY: STATE BAR NO: | FOR COURT USE ONLY |
|---|---|
| NAME: Daniel Yitzhak Simkin<br>FIRM NAME:<br>STREET ADDRESS: [redacted] Lucile Avenue AP[redacted]<br>CITY: Los Angeles STATE: CA ZIP CODE: 90026<br>TELEPHONE NO.: [redacted] FAX NO.:<br>E-MAIL ADDRESS: [redacted]<br>ATTORNEY FOR (name): | FILED<br>LOS ANGELES SUPERIOR COURT<br>MAR 23 2016<br>Sherri R. Carter, Executive Officer<br>By Bonnie Leck Dep.<br>Bonnie Leck |
| PEOPLE OF THE STATE OF CALIFORNIA<br>v.<br>DEFENDANT: Daniel Yitzhak Simkin DATE OF BIRTH: [redacted] | |
| **ORDER FOR DISMISSAL**<br>**(Pen. Code, §§ 17(b), 17(d)(2), 1203.4, 1203.4a, 1203.41, 1203.49)** | CASE NUMBER:<br>3VY00230-01 |

The court finds from the records on file in this case, and from the foregoing petition, that the petitioner *(the defendant in the above-entitled criminal action)* is eligible for the following requested relief:

1. The court **GRANTS** the petition for reduction of a felony to a misdemeanor (maximum punishment of 364 days per Pen. Code, § 18.5) under Penal Code section 17(b) and/or for reduction of a misdemeanor to an infraction under Penal Code section 17(d)(2) and reduces the following convictions:
   - ☐ ALL FELONY CONVICTIONS in the above-entitled action;
   - ☐ ALL MISDEMEANOR CONVICTIONS in the above-entitled action; OR
   - ☐ Only the following convictions in the above-entitled action *(specify charges and date of conviction)*:

2. The court **DENIES** the petition for reduction of a felony to a misdemeanor under Penal Code section 17(b) and/or for reduction of a misdemeanor to an infraction under Penal Code section 17(d)(2) for:
   - ☐ ALL FELONY CONVICTIONS in the above-entitled action;
   - ☐ ALL MISDEMEANOR CONVICTIONS in the above-entitled action; OR
   - ☐ Only the following convictions in the above-entitled action *(specify charges and date of conviction)*:

3. The court **GRANTS** the petition for dismissal regarding the following convictions under Penal Code ☒ § 1203.4, or ☐ § 1203.4a, or ☐ § 1203.41, or ☐ § 1203.49, and it is ordered that the pleas, verdicts, or findings of guilt be set aside and vacated and a plea of not guilty be entered and that the complaint be, and is hereby, dismissed for:
   - ☒ ALL CONVICTIONS in the above-entitled action; or
   - ☐ Only the following convictions in the above-entitled action *(specify charges and date of conviction)*:

4. The court **DENIES** the petition for dismissal regarding the following convictions under Penal Code ☐ § 1203.4, or ☐ § 1203.4a, or ☐ § 1203.41, or ☐ § 1203.49 for:
   - ☐ ALL CONVICTIONS in the above-entitled action; or
   - ☐ Only the following convictions in the above-entitled action *(specify charges and date of conviction)*:

5. In granting this order under the provisions of Penal Code section 1203.49:
   a. The court finds that the petitioner was a victim of human trafficking when he or she committed the crime.
   b. ☐ The court orders the relief described in section 1203.4, or
      ☐ The court orders the relief described in section 1203.4, with the following exceptions *(specify)*:



Form Approved for Optional Use
Judicial Council of California
CR-181 [Rev. January 1, 2016]

CR-181

| PEOPLE OF THE STATE OF CALIFORNIA v DEFENDANT: | CASE NUMBER: |
|---|---|
| DANIEL YITZHAK Simkin | BVY00230-01 |

6. If this order is granted under the provisions of Penal Code section 1203.4 or 1203.41:
   a. The petitioner is required to disclose the above conviction in response to any direct question contained in any questionnaire or application for public office, or for licensure by any state or local agency, or for contracting with the California State Lottery Commission.
   b. Dismissal of the conviction does not *automatically* relieve petitioner from the requirement to register as a sex offender. (See, e.g., Pen. Code, § 290.5.)

7. If the order is granted under the provisions of Penal Code section 1203.49, the Department of Justice is hereby notified that the petitioner was a victim of human trafficking when he or she committed the crime, and the relief ordered.

8. If the order is granted under the provisions of either Penal Code section 1203.4, 1203.4a, 1203.41, or 1203.49, the petitioner is released from all penalties and disabilities resulting from the offense except as provided in Penal Code sections 29800 and 29900 (formerly sections 12021 and 12021.1) and Vehicle Code section 13555. In any subsequent prosecution of the petitioner for any other offense, the prior conviction may be pleaded and proved and shall have the same effect as if probation had not been granted or the accusation or information dismissed. The dismissal does not permit a person to own, possess, or have in his or her control a firearm if prevented by Penal Code sections 29800 or 29900 (formerly sections 12021 and 12021.1). Dismissal of a conviction does not permit a person prohibited from holding public office as a result of that conviction to hold public office.

9. In addition, as required by Penal Code section 299(f), relief under Penal Code sections 17(b), 17(d)(2), 1203.4, 1203.4a, 1203.41, or 1203.49 does *not* release petitioner from the separate administrative duty to provide specimens, samples, or print impressions under the DNA and Forensic Identification Database and Data Bank Act (Pen. Code, § 295 et seq.) if petitioner was found guilty by a trier of fact, not guilty by reason of insanity, or pled no contest to a qualifying offense as defined in Penal Code section 296(a).

FOR COURT USE ONLY
SUPERIOR COURT OF LOS ANGELES COUNTY
CALIFORNIA

Date: 3/22/16

Rebecca Thomas
(JUDICIAL OFFICER)

# 10

# 10A

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440

## APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ New OUTSOURCING FACILITY
☐ Ownership Change (Provide current license number if making changes:) OUT_____
☐ 503a OR ☐ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1-3 & 4
☑ Non Publicly Traded Corporation – Pages 1-3 & 5
☐ Partnership - Pages 1-3 & 6
☑ Sole Owner – Pages 1-3 & 7

**GENERAL INFORMATION to be completed by all types of ownership**

Facility Name: BPI Labs, LLC

Physical Address: 12393 Belcher Road

City: Largo State: FL Zip Code: 33773

Telephone: 727-471-0850 Fax: 727-544-3595

Toll Free Number: 1-833-423-5243 (Required per NAC 639.708)

E-mail: complaints@belcherpharma.com Website: www.bpi-labs.com

Supervising Pharmacist: Cletis Kokkoulakis Nevada License #: 22391

**SERVICES PROVIDED**

Yes/No

☑ ☐ Parenteral
☑ ☐ Sterile Compounding
☐ ☑ Non Sterile Compounding
☑ ☐ Mail Service Sterile Compounding
☐ ☑ Other Services: _____

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only Date Processed: _____ Amount: $500 check 3450

**APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY** **Page 2**

FEI Number (From FDA application): 3015156709

Please provide the name of the facility as registered with the FDA and the registration number:
BPI Labs, LLC

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
BPI Labs

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Cletis Koukoulakis Nevada License Number: 22391

A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: N/A

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

**APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3**

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☐

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Cleris Koukoulakis

Print Name of Authorized Person

03/24/22

Date

**OWNERSHIP IS A SOLE OWNER.** All information relates to the person listed as the owner.

Owner's Name: Belcher Pharmaceuticals, LLC

Business Name: Belcher Pharmaceuticals, LLC

Current Business Address: 6911 Bryan Dairy Road

City: Largo State: FL Zip Code: 33773

Telephone: 727-471-0850 Fax: 727-544-3595

List any physician shareholders and percentage of ownership.

Name: N/A %:

Name: N/A %:

Name: N/A %:

Name: N/A %:

# Nevada State Board Of Pharmacy

(Licensee mailing address for window envelope)

THIS STUB IS YOUR RECEIPT

Date: 08/16/2022
Amount:
License #: 22391

Cletis M. Koukoulakis

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Pharmacist
Effective Date:08/16/2022
Expires:10/31/2023

Cletis M. Koukoulakis

License #
22391
Active

IDENTIFICATION ONLY
DOES NOT MEET POSTING REQUIREMENTS

Trim ID Card to fit your wallet

Cut Here

**NEVADA**
**STATE BOARD OF PHARMACY**
**Pharmacist**

Expires: 10/31/2023
STATUS: Active

License Type: Pharmacist
License #: 22391
Effective Date:08/16/2022

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENSED

Cletis M. Koukoulakis

**NONTRANSFERABLE**

POST THIS LICENSE PROMINENTLY IN A CONSPICUOUS PLACE

2634

Department of Health

# BPI LABS LLC BPI Labs

## License Number: PH32473

*Data As Of 5/1/2023*

| | |
|---|---|
| **Profession** | Pharmacy |
| **License** | PH32473 |
| **License Status** | CLEAR/ |
| **Qualifications** | Special Sterile CompoundingOutsourcing Facility |
| **License Expiration Date** | 2/28/2025 |
| **License Original Issue Date** | 12/10/2019 |
| **Address of Record** | 12393 BELCHER RD.<br>Suite 450 and 420<br>LARGO, FL 33773 |
| **Discipline on File** | No |
| **Public Complaint** | No |

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

# Company Management

bpi Labs

- **Jugal Taneja - Managing Member**

Responsible Corporate Officer of Belcher Pharmaceuticals.

BS in Mining & Petroleum, MSc in Mechanical Engineering, and MBA with over 30 years of experience managing healthcare and high-tech manufacturing companies, community banks, and petroleum energy industries.

Phone Number: (727) 471-0850 Extension 222, Email: jt@belcherpharma.com

- **Supriya Taneja - Vice President and General Counsel**

Juris Doctor, Law (Corporate Law concentration) with over 16 years in the healthcare industry. Licensed attorney specializing in health care regulatory and contract law for 12 years with a large firm. Her practice included both health law, including regulatory compliance, fraud and abuse, HIPAA, and licensure and certification, and corporate transactional matters for a range of healthcare providers, reviewing employment contracts and business sale agreements.

Phone Number: (727) 471-0850 Extension 241, Email: sst@belcherpharma.com

- **Fabio Lanzieri - President**

Leading marketing and sales. PhD in International Business and MBA with over 35 years of experience in pharmaceutical industry, with 20 years in executive roles.

Phone Number: (732) 339 3573, Email: fabiol@bpi-labs.com

- **Chandra Kasireddy - Director Technical Operations (Head of Operations Unit)**

Overseeing Sterile Drug Products Manufacturing and Technical Operations, Warehouse and Purchasing, Regulatory Affairs, Product Development, AR&D and Quality Control, Microbiology, and Maintenance.

Bachelor in Pharmacy with over 20 years of experience in production, validation / qualification, technology transfer, quality assurance, and operations in pharmaceutical products.

Phone Number: (727) 471-0850 Extension 289, Email: chandrak@belcherpharma.com

- **Mauricio Salazar - Chief Quality & Compliance Officer (Head of Quality Unit)**

Overseeing In-Process Quality Assurance, Product Release, Quality Systems, Training, Compliance, Complaints, Calibration, Validation, and EHS.

Industrial Engineer with over 20 years of experience in quality and compliance in pharmaceutical products, medical devices, and consumer goods.

Phone Number: (727) 471-0850 Extension 200, Email: mauricios@belcherpharma.com

- **Lana Radowick - Chief Financial Officer**

BS in Accounting and MBA (Strategic Management Concentration) with over 20 years of experience in public accounting, steel industry, and dental appliance manufacturing and distribution across 7 international entities in Europe, Asia, and Middle East.

Phone Number: (727) 471-0850 Extension 276, Email: lanar@belcherpharma.com

- **Cletis Koukoulakis, Pharm.D., C.Ph. - 503B Supervisory Pharmacist**

Over 20 years in Pharmacy Compounding Experience and Management, Pharmacy and Long Term Care Consulting.

Phone Number: (727) 471-0850 Extension 751, Email: cletisk@belcherpharma.com

**BPI Labs' associates possess over 100 years of combined experience in pharmaceuticals development, manufacturing, and distribution. Currently, approximately 50 employees work for BPI Labs, LLC; refer to attached organizational structure.**

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

**Section 1: General Information**

Pharmacy Name: BPI Labs, LLC

NV Pharmacy or Outsourcing facility license # (if applicable): N/A

Physical Address: 12393 Belcher Road

City: Largo State: FL Zip: 33773

Mailing Address (if different from physical address): 12393 Belcher Road, Suite 450

City: Largo State: FL Zip: 33773

Telephone: 727-471-0850 Toll Free # (NAC 639.708, NRS 639.23286): 1-833-423-5243

Fax: 727-471-0858 Contact Email: cletisk@belcherpharma.com

Website: www.bpi-labs.com

Nevada Business License # (if applicable) N/a

Supervising/Managing Pharmacist Name (NRS 639.220): Cletis Koukoulakis

Supervising/Managing Pharmacist NV Pharmacist Registration #: 22391

Name of Person with direct knowledge of compounding procedures: Cletis Koukoulakis

Email of Person with direct knowledge of compounding procedures: cletisk@belcherpharma.com

Telephone of Person with direct knowledge of compounding procedures: 727-471-0850 x 751

**Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)**

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☐ Low ☐ Medium ■ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ■ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
Currently produced one batch of Testosterone Pellets (225mg), distributed one order each to two FL wellness clinics.

Future plans for vials and prefilled syringe products to hospitals and diagnostic clinics.

We are a full generic drug manufacturer with 12 sterile products on the commercial market.

4. Will you be utilizing beyond use dates in excess of USP-797? ■ Yes ☐ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:

We follow the same robust stability program executed with our commercial products. The SOP (IQC-002) is included for review.

6. What laboratory performs this additional testing?

Name: Medizap (for e beam terminal sterilization of pellets only) -- Everything else in-house (full R&D, QC, Micro Labs)

Address: 600 B St Suite 300, San Diego, CA 92101

City: San Diego State: CA Zip: 92101

Telephone: (775) 386-6677

7. What is your procedure for visual inspection of compounded sterile products?

I have included the SOP (IPD-007) for visual inspection.

8. How often do you perform glove fingertip and medial fill testing?
Media fill testing is completed every six months. We have fully contained robotic filling isolators. There is glove access to the sterile areas without breaching the isolators, the gloves fingertips are tested with touchplates after every batch. The gloves are also tested for punctures before each batch begins.

9. What is your policy if an employee fails a glove fingertip or media-fill test?
It would not be an employee, but if one of the glove sets fails, then a full investigation would be initiated.

10. Describe your initial and annual training program for all personnel performing sterile compounding:
Initital and annual trainning SOP (ITD-001) is provided.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
Cleaning of Processing and Non-Processing Rooms SOP (IGN-028) is provided.

12. Who performs the sterile compounding process at your facility?
Robotic fill machines, assisted by Engineers and production technicians.

13. Who is responsible and accountable for the sterile compounding process at your facility?
All personel involved in the manufacturing process, 503B products under the supervision of the licensed pharmacist, with Quality Assurance checks and final release of batch.

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
Specifications and standard test methods for all containers and closures are generated for primary and secondary packaging components (testing types include description, physical tests, sterility and endotoxin (if applicable), and C of A check).

Final product shipping studies are performed (drop/ship test) utilizing primary and secondary containers.

Stability and freeze thaw studies are performed to document product behavior during temperature excursions.

| **Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)** | | |
|---|---|---|
| 1. What type of primary engineering controls will you be using in your facility?<br>N/A - No sterile Hazardous Compounding | | |
| 2. Is your BSC or CACI vented 100% to the outside? | ☐ Yes | ☐ No |
| 3. Do you have a negative pressure buffer room at your facility? | ☐ Yes | ☐ No |
| 4. Will you be compounding with antineoplastic HDs or HD API? | ☐ Yes | ☐ No |
| 5. If yes, are the drugs stored in an externally ventilated, negative pressure room? | ☐ Yes | ☐ No |
| 6. Will you be utilizing a closed system transfer device? | ☐ Yes | ☐ No |
| 7. If yes, list the name of the device: | | |
| 8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers? | | |
| 9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs? | | |

**Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)**

1. List the specific high risk sterile products that your facility compounds:
503B : Testosterone Pellets 225mg (10 count blister pack)

Current Commercial products include :
Hyoscyamine Sulfate Inj, USP 0.5mg/mL (NDC 54288-111-01),
Epinephrine Inj, USP 10mg/10mL (NDC 54288-120-01),
Epinephrine Chloride Nasal Solution 10mg/10mL (NDC 54288-123-01),
Tetracaine HCL Inj, USP 20mg/2mL (NDC 54288-127-01),
Phenobarbital Sodium Inj, USP 65mg/mL ( NDC 54288-136-01) ,
Phenobarbital Sodium Inj, USP 130mg/mL ( NDC 54288-137-01) ,
Papaverine HCl Inj, USP 60mg/2mL (NDC 54288-142-01),
Methylene Blue Inj, USP 100mg/10mL (NDC 54288-147-01),
Epinephrine Chloride Nasal Solution 30mg/30mL (NDC 54288-154-01)

2. What sterilization methods are utilized at your facility?
A 3 step 0.22 micron filtration process with one time use sterile bags and tubing. Autoclave for any glassware or components used during the mixing process.

3. Does your facility utilize biological indicators? ☑ Yes ☐ No

4. If yes, describe how they are utilized:
In the robotic machines, a risk assessment is established. BIs are placed , VPHP cycles are run, results are assessed and guidelines are established after achievieving acceptable levels.

BIs are also utilized n the component prep and filter tubing process, those that undergo autoclaving.

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Cletis Koukoulakis, Pharm.D.
Name of Person who Completed the Form

Pharmacist and Manager of Medical Affairs
Title

Signature (copies or stamps not accepted)

04/27/23
Date

| Board Use Only | Date Received:_____ Date Approved:_____ Approved By:_____ |
|---|---|

# STATE OF FLORIDA
# DEPARTMENT OF HEALTH
# INVESTIGATIVE SERVICES
## 503b Outsourcing Inspection

File # 26555
Insp # 185806

| NAME | PERMIT NUMBER | DATE OF INSPECTION |
|---|---|---|
| BPI LABS LLC | 32473 | 04/03/2023 |
| **DOING BUSINESS AS** | | |
| BPI LABS | | |
| **STREET ADDRESS** | **TELEPHONE #** | **EXT** |
| 12393 BELCHER RD. Suite 450 and 420 | 727-471-0850 | |
| **CITY** | **COUNTY** | **STATE/ZIP** |
| LARGO | PINELLAS | FL/33773 |

**Additional Information**

**Business Operation Hours**

| | |
|---|---|
| | |

**Registered Pharmacist / Intern / Tech**

| | |
|---|---|
| | |

**ACS Manager**

| | |
|---|---|
| | |

**Optional Information**

| | |
|---|---|
| | |

**Basic License Data - PSD**

| | |
|---|---|
| | |

**License Relations**

**Pharmacy Affiliate**

| | |
|---|---|
| TANEJA, MANJU | License # |
| TANEJA, SUPRIYA | License # |

**RX DPT MGR/COR/POR**

| | |
|---|---|
| KOUKOULAKIS, CLETIS MICHAEL | License # 36693 |

## 503b - Outsourcing Inspection

**Quality**

| | |
|---|---|
| Firm has an independent Quality Control Unit | Yes |
| The QC unit has the authority and responsibility to approve or reject all components, drug product containers or closures, end process materials, packaging materials, labeling and drug products. | Yes |
| QC unit reviews and approves/rejects: SOP's, Batch Records (completeness and accuracy, components, API's, materials, OOS results | Yes |
| Investigations are conducted within time limits specified per SOP<br>*1 batch Testosterone 225mg pellets released since previous inspection, no complaints related to batch.* | N/A |
| All written quality procedures are current and approved | Yes |
| The QC unit follows their procedures | Yes |
| QC unit personnel are qualified through training and experience. | Yes |
| The production batch record and release test results are reviewed for accuracy and completeness prior release of finished product<br>*Reviewed Batch Record for Testosterone 225mg pellets.* | Yes |

**Facilities and Equipment**

| | |
|---|---|
| The facility design is suitable for compounding sterile products | Yes |
| The layout and organization of the facility is designed to prevent contamination and mix ups. | Yes |
| The control of air pressure, dust, humidity and temperature is adequate for the manufacturing, processing, storage or testing of drug products | Yes |
| Pressure gauges that monitor pressure differentials are calibrated | Yes |

# 503b Outsourcing Inspection

Insp # 185806 BPI LABS LLC File # 26555

| | |
|---|---|
| The facility is maintained in a clean and sanitary condition | Yes |
| Certifications conducted under dynamic, worst case conditions with the maximum number of personnel allowed per SOP present | No |
| The facility has written procedures that describe in sufficient detail the cleaning schedule, methods, equipment and material | Yes |
| The facility has a procedure for rotating cleaning solutions | Yes |
| Sporicidal agents are used . How often<br>*Monthly* | Yes |
| The facility has documentation of the effectiveness of the cleaning solutions | Yes |
| Primary and secondary engineering controls currently certified<br>*No PEC's, particle count testing in rooms, ISO 8 rooms for compounding of pellets.* | Yes |
| Ceiling tiles are clean room grade and gasketed and sealed/clipped. | N/A |
| Air return vents are not blocked | Yes |
| HEPA filters are all leak tested<br>*In house HEPA leak testing.* | Yes |
| Compounding of hazardous drugs is clearly separated from non hazardous drugs to prevent cross contamination.<br>*Testosterone Pellets compounded in suite that is used for Testosterone only.* | Yes |
| All equipment has written procedures for use. | Yes |
| Facility has documentation of equipment calibration, maintenance, cleaning. | Yes |
| All equipment is validated for its intended use. | Yes |
| Refrigerators and freezers are monitored with a calibrated thermometer. | Yes |
| Documentation of training personnel on use of equipment. | Yes |
| Surfaces that contact materials or finished goods non-reactive, non-adsorptive and non- additive | Yes |

**Personnel Qualification**

| | |
|---|---|
| All Personnel involved in the preparation and handling of csp's are trained and qualified in their roles. | N/A |
| Facility has a written training program that describes the required training, frequency of training and process for evaluating the performance of individuals involved in sterile compounding. | N/A |
| Facility has documentation that compounding personnel have the required skills necessary to perform their assigned task | Yes |
| Compounding personnel receive ongoing periodic GMP training by GMP trainers. | Yes |
| Are GMP trainers qualified through experience and training. | Yes |
| Prior to beginning to prepare CSP's personnel have completed training and have demonstrated proficiency in the principles and hands on skills of aseptic manipulations.<br>*Firm only produces pellets which are sterilized by E Beam after packaging* | N/A |
| Compounding personnel have ongoing training for specific tasks they are authorized to perform. | Yes |
| Personnel have been periodically trained in core competencies, visual observation is conducted to confirm personnel have necessary skills (i.e. Hand hygiene and garbing, aseptic manipulations, cleaning and disinfecting). | N/A |
| Personnel sampling including GFT is conducted after compounding and documented on each batch record. | N/A |
| Personnel have completed media fill simulations for all aseptic compounding under the most difficult and challenging processing conditions which include the most manipulations/units, most complex flow of material, longest time to compound and all breaks. | N/A |
| Personnel are retrained and requalified after failure of media fill, GFT or batch failures. | N/A |

**Environmental Monitoring**

| | |
|---|---|
| Facility has an environmental monitoring program. | Yes |
| Air quality is monitored regularly using volumetric air sampling to ensure the environment remains suitable for sterile compounding. | Yes |
| Settling plates are used during compounding to monitor the quality of air during compounding processes and documented in the batch records. | Yes |
| Surface sampling is conducted after each batch prior to cleaning and documented on batch records. | Yes |
| Surface sampling is routinely conducted in all classified spaces in those locations identified to be at highest risk of contamination | Yes |
| Media used in environmental and personnel monitoring has been shown to promote the growth of microorganisms and contains agents to neutralize cleaning solutions and disinfectants. | Yes |
| Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment. | Yes |
| Adverse changes in the environment are investigated and promptly remediated.<br>*No growth has occurred in the rooms.* | N/A |
| Alert and action levels for CFU counts have been established in SOP's for the facility. | Yes |
| Air pressure differentials are continuously monitored and demonstrate that a cascading pressure differential is maintained throughout the compounding area during production of sterile compounding.<br>*Manual documentation* | Yes |

**Materials**

| | |
|---|---|
| Facility has a quality agreement with API suppliers to ensure all API's are manufactured in registered FDA facilities. | Yes |
| Facility tests API's for identity, strength and purity to confirm the specifications in the Certificate of Analysis. | Yes |
| Facility maintains and follows SOP's for testing of incoming materials. | Yes |

# 503b Outsourcing Inspection

Insp # 185806 | BPI LABS LLC | File # 26555

| | |
|---|---|
| Facility has appropriate sterile PPE<br>*Firm only produces pellets which are sterilized by E Beam after packaging* | N/A |
| Materials for cleaning the PEC's are sterile and the effectiveness is validated.<br>*No PEC's.* | N/A |
| Filters used for sterilization have documentation that they are compatible with the product, are pharmaceutical grade, non-pyrogenic and capable of sterilizing the intended volume. | N/A |
| Integrity testing is conducted on all filters used to sterilize product. | N/A |
| All materials are quarantined until approved by the QC department. | Yes |
| Written procedures identify storage times beyond which materials must be reexamined before use. | N/A |
| Release of re tested material clearly identified for reuse. | N/A |
| Written procedures identify steps in the materials for production. | Yes |
| Written procedures include release by QC, documentation of correct weight or measure and proper identification of containers. | Yes |

**Production**

| | |
|---|---|
| Materials are sanitized prior to introduction into the clean room | Yes |
| All glassware is depyrogenated and cycles are validated and documented. | N/A |
| Autoclaved cycles are properly validated with BI's. | N/A |
| Sterilization methods are validated<br>*Ebeam.* | Yes |
| All components are identified on batch records and traceable to the finished product. | Yes |
| SOP's identify hold times for depyrogenated glassware and the hold times have been validated. | N/A |
| Deviations and OOS's are adequately documented and thoroughly investigated. | N/A |
| Facility maintains complete batch records for all compounded sterile products | N/A |
| Facility maintains separate, complete, readily retrievable records of dispensing into the State of Florida | Yes |
| Written procedures indicate how and who verifies that correct containers and packages are used for the finished product. | Yes |
| All finished products are held in quarantine until QC has completed testing and releases the batch. | Yes |
| Personnel who conduct visual inspection of finished products have been qualified through training and yearly eye exams. | N/A |
| Firm has an SOP for adverse event reporting to FDA | Yes |
| Firm has record of adverse event reports submitted to FDA | N/A |

**Labeling**

| | |
|---|---|
| Written procedure specify who is authorized to issue labels. | Yes |
| Written procedure specify how labels are issued, used, reconciled with production, returned when unused, and the specific steps for evaluation of any discrepancies. | Yes |
| Written procedures call for the destruction of excess labeling on which lot and control #'s have been stamped or imprinted. | Yes |
| Written procedures require that representative samples of units be visually examined upon completion of packaging to verify correct labeling. | Yes |
| Drug labels include the statement "this is a compounded drug, the name, address and phone # of the facility | Yes |
| The label of the drugs contain the lot or batch #, the established name of the drug, dosage form and strength, quantity or volume, the date the drug was compounded, the expiration date, storage and handling instructions, NDC # (if available), the statement "not for resale" and a list of active and inactive ingredients identified by established name and the quantity or proportion of each ingredient and route of administration. | Yes |
| The label or container contains the following: www.fda.gov/medwatch and 1-800-FDA-1088 | Yes |
| Written procedures detail how equipment is to be checked immediately prior to use for removal of any labels and labeling from prior print operations.<br>*10 Pellets into blister, labeled and sealed.* | Yes |

**Laboratory**

| | |
|---|---|
| Contract labs are FDA registered | Yes |
| Facility has qualified their contract labs | Yes |
| All products have stability studies to justify the BUD<br>*Testosterone 225mg BUD 1 year with studies.* | Yes |
| Stability studies, microbial effectiveness testing on the preservative, container closure studies and sterility testing have been conducted to ensure the CSP continues to meet all specifications over the intended shelf life of the product. | N/A |
| Sterility testing for all batches is conducted using a USP 71 test. | Yes |
| Method suitability has been conducted for all products | N/A |
| Endotoxin testing is conducted on all batches. | Yes |
| Potency is conducted on all batches. | Yes |
| Appropriate # of articles/volume is tested for sterility | N/A |
| Facility maintains and follows SOP for product release. | Yes |
| Facility has approved finished product specifications for all csp's. | N/A |

## Remarks:

Facility has compounded and distributed 1 lot of Testosterone 225mg pellets. Dedicated Testosterone Suite.
Inspection completed with Mauricio Salazar and Cletis Koukoulakis.

# 503b Outsourcing Inspection

Insp # 185806

BPI LABS LLC

File # 26555

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

STAIKOS, GILLIAN

Date:4/3/2023

Representative:

Cletus Koukoulakis

Date:4/3/2023

| SOP No. | Title | Revision No. |
|---|---|---|
| ITD-001 | TRAINING SYSTEM | 04 |

| Prepared By / Date | Reviewed By / Date | QA Approved By / Date | Effective Date |
|---|---|---|---|
| Sanja Mizic 07/12/22 | Sridevi G.V 07/13/22 | M. Salazar 07/18/22 | JUL 2 7 2022 |
| | | | Change Control No. |
| Title: QA Group Leader | Title: QST C Supervisor | Title: CQCO | I-22417 |

## 1.0 PURPOSE

To outline the procedure for training personnel to perform their job functions in compliance with cGMP requirements and all federal and state regulations applicable to BPI Labs. This document will describe training requirements and procedures in terms of new employee orientation, continuing training program, cGMP training, new / revised documents, and other training, and qualification techniques.

## 2.0 SCOPE

This procedure applies to all personnel employed at the company as full time, part time, or temporary basis.

Training activities are coordinated by the Quality Assurance Department.

## 3.0 RESPONSIBILITY

3.1 All employees are responsible to attend the new employee orientation at the time of hiring, conduct training on a continuous basis as per approved curriculum and qualification technique, attend to cGMP training at least once a year, and perform training on new and revised documents, as required.

3.2 Quality Assurance Department is responsible for:

3.2.1 Determining the training requirements and qualification techniques (when applicable) for employees together with department managers.

3.2.2 Maintaining training curriculums and qualification techniques (when applicable) for job functions.

3.2.3 Coordinating and conducting new hire training with department managers.

3.2.4 Conducting cGMP training for all employees at least once a year.

3.2.5 Coordinating and/or conducting training of existing employees with department managers.

3.2.6 Maintaining training records for all employees.

3.2.7 Identifying and training trainers within the company.

3.2.8 Identifying and hiring external training resources when required.

3.2.9 Ensuring trainers possess the necessary qualifications to conduct training.

3.2.10 Assessing training effectiveness.

3.2.11 Providing training tracking and trending information for Management Reviews.

3.3 Department Managers are responsible to:

| SOP No. | Title | Revision No. |
|---|---|---|
| ITD-001 | TRAINING SYSTEM | 04 |

3.3.1 Ensure that all new employees attend to the new employee orientation at the time of hiring.

3.3.2 Assure that their employees are trained on the documents and job skills relevant to their area.

3.3.3 Ensuring their personnel do not perform job tasks or functions for which they are not appropriately trained.

3.3.4 Creating with the assistance of Quality Assurance training curriculums and qualification techniques for their employees.

3.3.5 Conducting on the job training of employees.

3.3.6 Identifying via performance evaluations training deficiencies of their reportees.

3.3.7 Coordinating and conducting training to promptly resolve training deficiencies of their reportees.

3.4 BPI Labs management is responsible for providing the necessary resources to implement a training system compliant with cGMPs and all federal and state regulations applicable to the company.

## 4.0 REFERENCES

4.1 21 CFR Part 211.25 Personnel qualifications

4.2 21 CFR Part 820.25 Personnel

4.3 SOP IQA-002 Document Control System

4.4 SOP IPD-017 Qualification and Validation of Inspection Processes

4.5 Form ITD-001-F1 Training Record Form

4.6 Form ITD-001-F2 Self Training Record Form

4.7 Training Curriculum TC-IGN-001 All Departments - (All Employees) New Employee Training

4.8 Training Curriculum TC-IGN-002 All Departments - (All Employees) Annual Employee Training

4.9 Training Curriculum TC-IGN-003 All Departments - (All Employees) Biennial Employee Training

4.10 Qualification Technique QT-ITD-001 Training and Development - cGMP Training

4.11 Qualification Technique QT-IEH-002 EH - General Industry Safety Training

## 5.0 ATTACHMENTS

Not Applicable.

## 6.0 PROCEDURE

6.1 General requirements:

6.1.1 Documentation and Filing of Training Records:

6.1.1.1 A training record (Forms ITD-001-F1 and ITD-001-F2) is documented accordingly for any type of training upon training completion. Form ITD-001-F1 is used to document all trainings other than self training. Form ITD-001-F2 is utilized to document self training only. Following sections shall be completed:

6.1.1.1.1 Topic or Document Name.

6.1.1.1.2 Document Number and its Document Revision, when applicable.

6.1.1.1.3 Type of Training (what kind of training).

6.1.1.1.4 Method of Training (how is the training conducted). This is not applicable on Form ITD-001-F2.

6.1.1.1.5 Trainer. This is not applicable on Form ITD-001-F2.

6.1.1.1.6 Date of Training.

6.1.1.1.7 Employee Name, Department, and Signature.

6.1.1.1.8 Acknowledgement of Training Understanding. This is not applicable on Form ITD-001-F1.

6.1.1.2 Upon training completion, employees, department head, or designee submit all original training records to Training and Development.

6.1.1.3 Training and Development verifies the training record for accuracy and completeness and files training records appropriately.

6.1.1.4 Training and Development keeps all employees training records and any other document pertaining to training.

**NOTES:**

**a) Training curriculums and qualification techniques are also considered a training record since these documents are used by personnel to acknowledge the completion of self training.**

**b) The signature log included in the batch and packaging records is also considered a training record since the personnel involved during the manufacturing, packaging, and inspection activities of the product use this record to acknowledge their competence and understanding of the work to be done and the precautions required during the execution of each activity.**

6.2 Type of Training:

6.2.1 New Employee Orientation:

6.2.1.1 At the time of hiring all new employees are required to attend the new employee orientation program following general and specific training.

6.2.1.2 New Employee Training (General and Specific Training):

6.2.1.2.1 General Training consist in an overview and completion of respective forms, overview of general safety, overview of cGMPs, overview of quality systems, and a general SOP self training session as per Training Curriculum TC-IGN-001. A combination of group training and self-training method is used as part of the training session and discussion.

6.2.1.2.2 Discussion and completion of respective forms (i.e., Employee Signature List, Employee Screening Questionnaire, Respiratory Medical Evaluation Questionnaire, Respiratory Fitness Test, Company Safety Policies) is coordinated by Training and Development and acknowledged on respective Training Curriculum TC-IGN-001.

6.2.1.2.3 An overview of federal regulations, current Good Manufacturing Practices based on 21 CFR Parts 210, 211, 820, and 4, WHO Guidelines – Hormones, FDA Guidance – 503B, DBPR, DOH, internal audits, warning letters, and annual trend of 483s, overview of general safety, and overview of quality systems is coordinated by Training and Development and documented on respective Training Curriculum TC-IGN-001.

6.2.1.2.4 General SOP Self Training (coordinated by Training and Development) identifies a list of SOPs / documents required to complete general SOP self-training session. New employees are required to read each SOP / document according to section 6.3.1; self training record is documented upon completion using the respective Training Curriculum TC-IGN-001. Training and Development coordinates questions and answers session upon self training session completion to ensure trainee has comprehended the material read.

6.2.1.2.5 Upon completion of General cGMP Training, General Department Core Training and Specific Training Curriculum are issued to employee on the respective employee's training folder for execution. Respective training is coordinated by each department supervisor or designee based on respective training curriculums and depending on functions to be performed.

6.2.1.2.6 An assessment is done by the department head or designee based on the person's education, job experience, and previous training to determine the extent of the training and its method of training (i.e., self-training, on the job training).

6.2.1.2.7 Conducted self-training is documented on respective General Department Core Training Curriculum, and Specific Training Curriculum assigned to employee's training folder. In addition, conducted on the Job / Hands on Training is documented using Form ITD-001-F1.

6.2.1.2.8 Upon completion of respective training curriculums, the department head or designee informs by any means (i.e., via e-mail) to Training and Development.

6.2.1.2.9 Training and Development ensures that all trainings were properly performed and documented, and acknowledgement of completion of

respective training curriculums is performed by employee, supervisor and training group accordingly by placing signatures and date on respective section at the end of Department and Specific Training Curriculums (refer to section 6.5 for details of training evaluation).

6.2.1.2.10 After acknowledgement of completion of training curriculum, final release is performed. Employee is required to sign on respective section of Training Curriculum TC-IGN-001 (i.e., Completion of Department General Training section). Lastly, employee and supervisor are required to perform respective acknowledgment of completion of new employee training by placing respective signatures and date on the Acknowledgement of Completion of New Employee Training section using Training Curriculum TC-IGN-001. Training Group releases the trainee for normal activities by informing the department head or designee by any means (i.e., via e-mail) if all training requirements were met using TC-IGN-001.

**NOTE: As a general practice, new employees should complete the new employee orientation training ideally within 3 months from their hiring date.**

6.2.2 Biennial Training (Continuing Training Program):

6.2.2.1 Training curriculums are used as a tool to assure that training is performed on a continuing basis. They include the list of documents and skills training that are required to perform assigned position adequately. Training curriculums need to be executed by employees at least once every two years.

6.2.2.2 Each department supervisor prepares training curriculums by position following SOP IQA-002, contacts at the beginning of the period his / her employees to plan for the execution of the training curriculum throughout the two-year period, identifies additional training needs, updates training curriculums as needed, and coordinates any extra training not included in the training curriculum.

6.2.2.3 After completion of respective training curriculum, acknowledgement of completion of training curriculum is performed as part of employee evaluation. Signature and date are placed by employee, supervisor, and training group on respective section as part of an overall evaluation of the training curriculum (refer to section 6.5 for details of training evaluation).

**NOTES:**

a) **Employee's training folder is prepared using the training plan. The training plan is established after discussing with the supervisor / manager to include all the applicable training curriculums based on the employee's job functions and responsibilities.**

b) **Training and Development group prepares a training folder using the training plan by employee including the applicable training curriculums to be executed during the respective training period (i.e., TC-IGN-002, TC-IGN-003, General Department Training Curriculum). Applicable training curriculums are distributed to respective employee's training folder based on each employee's applicable job functions and responsibilities.**

**c) The Training and Development group keeps track of the progress of the employee's biennial training curriculum on a quarterly basis.**

**d) Training curriculum impact assessment is performed each time a training curriculum is revised via change control in order to assess that the respective document is not impacted by the change and to determine the need of distribution to respective training folders (i.e., if an additional SOP is added to the training curriculum, that training curriculum might not require to be distributed within the training period if respective training has been completed as part of change control).**

**e) Training plan is assessed for the employees who are transferred to other functions or departments. The training plan is updated accordingly for such employees and the progress about completion of the issued training curriculums as per the updated training plan is tracked by Training and Development group for completeness. As a general practice, this training should be completed ideally within 3 months from the transfer / new functions date.**

6.2.3 Annual Training (Update of Forms, cGMP Training and General Safety Training):

6.2.3.1 Update of Forms (i.e., Employee Signature List, Employee Screening Questionnaire, Respiratory Medical Evaluation Questionnaire, Respiratory Fitness Test, Company Safety Policies) are discussed and coordinated by Training and Development at least once a year and acknowledged by employee on respective Training Curriculum TC-IGN-002.

6.2.3.2 cGMP training is conducted for all employees by Training and Development at least once a year as per Training Curriculum TC-IGN-002. Topics are selected from federal regulations (i.e., 21 CFR Parts 210, 211, 820, and 4, WHO Guidelines – Hormones, FDA Guidance – 503B, DBPR, DOH, internal audits, warning letters, and annual trend of 483s), documentation practices, data integrity, compliance programs, among others.

6.2.3.3 General Safety Training is conducted for all employees by Training and Development at least once a year as per Training Curriculum TC-IGN-002. Training consists of a refreshment of the company's safety program standard operating procedures.

6.2.3.4 Conducted cGMP and General Safety trainings are documented on respective group training form ITD-001-F1, and acknowledgement of completion of training is documented by employee on training curriculum TC-IGN-002 located on each employee respective training folder.

6.2.3.5 Completion of Training Curriculum TC-IGN-002 is acknowledged by employee, supervisor, and training group by placing respective signature and date on "Acknowledgement of Completion of Annual General Employee Training Section" at the end of respective training curriculum.

6.2.4 New / Revised Documents Training:

6.2.4.1 As a general practice, training on new / revised documents is applicable at least to SOPs, Forms, STMs, Master Batch Records, and Master Packaging Records before they become effective.

6.2.4.2 When a document is written or revised and that document is needed by users that are not the authors, reviewers, or approvers, training should be conducted.

6.2.4.3 During the change control approval process, area management and Quality Assurance evaluate the impact of changes against the established training curriculums in the quality system and training needs and decide the extent and the method of training (i.e., individual training, group training, practical training) as well as determine all the individuals affected with the change; this decision is documented on the change control form. Upon training notification from Quality Assurance, area management or designee coordinates the execution of the training ideally in not more than fifteen (15) business days from the training notification date.

6.2.4.4 Training sessions can be coordinated by the subject matter expert (i.e., author) depending on the topic of the activity (i.e., change control system). A training assessment quiz might be administered to the employees, as required by trainer, Quality Assurance, and / or area management.

6.2.4.5 Upon completion of the training the designee informs Training and Development / Document Control and submits all training records accordingly.

6.2.4.6 Each department destroys the training document copies (training copy) upon training completion. Under no circumstances the training copy can be used for reference, nor can it replace the official effective copy.

6.2.4.7 Once training requirements are met, Training and Development and Document Control confirm each other to ensure that the document can be made effective.

6.2.4.8 Only employees trained in the most recent version of the document can be released to perform the work described in the document.

6.2.4.9 Following the initial training period, the department supervisor conducts training of the missing employees (i.e., for those who are on short term disability or leave) and documents this activity in a separate training record.

6.2.4.10 Department head is responsible for assuring that all reporting personnel are trained on job-related documents.

**NOTES:**

**a) Minor changes to documents such as but not limited to editorial updates to documents, creation or revision of documents used for reference only (i.e., official list), change in revision number and revision history without any change in the content of the document as a result of triennial review, and change due to typographical errors, might not require training. This decision is documented on the change control form.**

**b) Major changes to documents such as but not limited to addition of equipment in master batch records and master batch packaging records, update of processes and parameters in master batch records and master batch packaging records, revision of analytical procedure in test methods, update of practices in SOPs, and implementation of new Forms require training.**

6.2.5 Other Training:

6.2.5.1 Department supervisor, Training and Development and / or Quality Assurance may determine that one or more employees need training or retraining. If that is the case, a trainer is designated, and a training session is conducted. Whenever retraining is conducted the training record should be identified as such.

6.2.5.2 Department supervisors identify outside training needs for their employees, as required, and coordinate the registration for the courses. Employees submit copy of the training certificate to Training and Development department upon completion.

6.3 Method of Training:

6.3.1 Self Training:

6.3.1.1 Training conducted by one person and considered as a read and understanding session. Training shall be performed following these steps:

6.3.1.1.1 Overview the document briefly. Get familiarized with it. Review its sections and any additional parts of it (i.e., forms, charts, tables, etc.). Perform these activities before starting reading.

6.3.1.1.2 Read slowly and if possible loud enough that one can hear himself / herself.

6.3.1.1.3 Ensure to understand what it is read. Have a paper and pen to write down any question and/or suggestion to be later discussed with supervisor, co-worker, trainer, or designee.

6.3.1.1.4 A self training record (Form ITD-001-F2) is documented accordingly.

**NOTE: Training curriculums and qualification techniques can be used to acknowledge the completion of self training. In these cases, Form ITD-001-F2 is not required.**

6.3.1.2 Upon training completion, self training conducted by the employee is evaluated by discussing respective topic between employee and supervisor or designee (refer to section 6.5 for details of training evaluation). Respective evaluation is documented accordingly in the respective section of the training record as follows:

6.3.1.2.1 For self training using Form ITD-001-F2, supervisor or designee performs evaluation of respective topic (s) with employee by asking random questions of the topic (s) to the employee for discussion in order to measure the level of understanding. At the end of the evaluation, supervisor or designee acknowledges that the employee has understood respective material read on the appropriate section of the form.

6.3.1.2.2 For self training using training curriculums and qualification techniques, supervisor or designee performs evaluation of respective topic (s) with employee during the training period by asking random questions of the topic (s) to the employee for discussion and by assessing performance of the employee related to job functions and assigned tasks, in order to confirm the appropriateness of the extent of the training in line with the work responsibilities. Overall evaluation and acknowledgment of completion of the training is performed by the supervisor or designee

using the respective section of the training curriculums and qualification techniques at the end of the training period.

**NOTE: If during the training evaluation performed by the supervisor or designee an opportunity of additional training is identified to enhance the level of understanding of the topic, the extent and method of training are determined and coordinated accordingly as per this SOP.**

6.3.2 Group Training:

6.3.2.1 Training conducted between two or more persons and considered as a read, understand, and discussion session. Trainer can be the second person.

6.3.2.2 A training record (Form ITD-001-F1) is documented accordingly.

6.3.3 On The Job Training / Hands-on Training / Practical Training:

6.3.3.1 On the Job Training (OJT) is a training that takes place while employees are actually working; this means the skills are gained while trainees are carrying out their jobs. This training can be executed following below tasks. Equivalent approaches are considered acceptable as long as the process leads to proficiency for specific job tasks.

6.3.3.2 Department head or designee assigns a trainer to work with the trainee.

**NOTE:**

**Authorized Trainers: BPI Labs employees or contractors who have the education, training and experience or any combination thereof, that enables them to conduct training. This includes but is not limited to:**

**a) The training coordinator.**

**b) External trainers upon approval of Quality Assurance via verification of their credentials.**

**c) All supervisors and managers after completion of their training curriculum unless pre-employment qualifications to conduct training are provided and approved by Quality Assurance.**

**d) Personnel designated by department managers or supervisors upon approval of Quality Assurance via verification of qualifications that include, but are not limited to:**

- **Submission of a resume.**
- **Completion of the training curriculum for their position.**
- **Completion of the qualification technique for the unit operation, module or technique.**
- **Verifiable experience of outside training (certifications, diplomas, etc.)**

6.3.3.3 The trainer shall be an employee well experienced, knowledgeable, and fully trained on the topics to be covered and shall have good training / communication skills.

6.3.3.4 The trainee performs a self training according to section 6.3.1 for all documents included in the training curriculum in addition to others assigned by the Department head or designee.

6.3.3.5 The trainer performs the job and the trainee observes. The trainer goes over the procedure together with the trainee and in the work area showing where every equipment, files, documents, or any other item related to the training are located and, when applicable, its function and/or operation. Every practice, and method, is followed by the trainee with the written procedure and discussed / explained by the trainer, as needed. Trainer and trainee review the written procedures. This step can be repeated, as required. A training record (Form ITD-001-F1) is documented accordingly and identified as On the Job Training.

**NOTE: As part of execution of qualification techniques, these documents are used to acknowledge the completion of this step. In these cases, Form ITD-001-F1 is not required.**

6.3.3.6 Trainee performs the job with the reference of the written procedure, in presence of the trainer, and with the help and guidance of the trainer.

6.3.3.6.1 The trainer observes and verifies performance and execution against the written procedure. The activity or task performed are initialed / signed and dated by the trainee and trainer using appropriate records according to the activity. This record confirms that trainer has been present at the time of the task execution.

**NOTE: During execution of qualification techniques, these documents are used to acknowledge the completion of this step. In these cases, Form ITD-001-F1 is not required.**

6.3.3.6.2 Trainer conducts a question and answer session with the trainee. The trainer clarifies any doubt. Trainer verifies for comprehension.

6.3.3.6.3 This step can be performed as needed at the discretion of the trainer and department head according to performance observed and taking into consideration the trainee's performance, experience, and previous training. In case additional training is needed, trainer informs department head or designee for further instructions.

6.3.3.7 The trainer informs by any means (i.e., via e-mail) to the department head or designee about the completion of on the job training program.

6.4 Qualification Techniques:

6.4.1 Qualification techniques are used by department supervisors as a tool to qualify an employee in regards to a specific unit operation, module, or technique (i.e., sterile filtration, aseptic filling, sampling, HPLC analysis) and to acknowledge his / her competence and qualification on a continuous basis.

6.4.2 Qualification techniques records include, but are not limited to, the list of reference documents, the list of related equipment and measuring devices, the reference for the on the job training completion, and the approval of the exercise.

6.4.3 Each department supervisor prepares qualification techniques as needed based on the criticality of the unit operation, module, or technique, and coordinates execution with the selected employee.

6.4.4 Qualification techniques need to be executed by personnel at least once every three years according to the overall evaluation by the supervisor of the employee's performance throughout the entire certification process taking in consideration job performance, quality / accuracy of work, dependability, ability to work as part of a team, and compliance with company procedures. Acknowledgement of completion of training for the qualification technique unit operation / module is performed by placing employee and supervisor's signatures and date at the respective section of the Qualification Technique Form. Training and Development group assigns the re-certification due date for employees based on above criteria and supervisor's recommendations.

**NOTES:**

**a) Qualification Technique re-certification for production visual inspection of injections needs to be executed by personnel at least once every year according to the guidelines outlined on SOP IPD-017.**

**b) The qualification techniques for cGMP and Safety (i.e., QT-ITD-001 and QT-IEH-002, respectively) are executed once every two years and annual refreshment training is completed every year to be up to date on all the training needs from time to time.**

6.4.5 The qualification techniques matrix shows the core / primary activities that qualified personnel (i.e., subject matter experts) can perform unsupervised.

**NOTES:**

**a) Training and Development group prepares a training folder by employee including the applicable qualification techniques to be executed during the respective certification period. Respective Qualification Technique Matrix is updated accordingly, and training folders are distributed to respective supervisor or designee upon request.**

**b) As a general practice, the employees should complete the initial qualification technique ideally within 3 months from the date of issuance.**

**c) Qualification Technique impact assessment is performed each time a qualification technique is revised via change control in order to assess that the respective document is not impacted by the change and to determine the need of distribution to respective training folders (i.e., if an additional SOP is added to the qualification technique, that qualification technique might not require to be distributed within the training period if respective training has been completed as part of change control).**

**d) As part of qualification technique recertification exercise, whenever the employee is unable to execute hands on / on the job training verification (Section – 4, Training Reference of Execution by Trainee) at the time of the recertification due period, then the employee must complete the self-training related to the respective qualification technique and inform Training and Development group accordingly to acknowledge this situation in the training system (i.e., Qualification Technique Matrix and corresponding qualification technique). The hands on / on the job training is executed once the activity / unit operation becomes available as per the department's needs.**

**e) The qualification technique recertification due date is assigned from the date of issuance of the qualification technique for the execution purposes. Whenever the qualification technique is recertified,**

**Training and Development group updates the Qualification Technique Matrix and re-issues the respective qualification technique for the next period.**

**f) On a quarterly basis, Training and Development group verifies the Qualification Technique Matrix for the employee's pending recertification for the next quarter. The Training and Development designee prepares a list of all the employees due for recertification and communicates to the employees and the supervisor to inform them about the qualification technique recertification. This list is monitored and updated on a monthly basis by the Training and Development group until completion.**

6.5 Evaluation of Training:

6.5.1 Training and Development may, at its sole discretion, conduct an evaluation at any time of any part of the training process (i.e., training sessions, trainees, trainer, training material, retraining, repetitive human mistakes) to verify training effectiveness. Evaluation of training process involves the identification of unwanted trends that are discussed with supervisors and managers in order to determine the further action needed to enhance the performance of the personnel.

6.5.2 Supervisor or designee is fully responsible to evaluate training effectiveness of his / her employees routinely by assessing the job performance, quality and accuracy of work, consistency of work, among others, in order to understand the adequacy of the extent and method of training. The training evaluation is verified continuously and documented in all the available records in the quality system related to training and specific job functions.

6.5.3 In order to further measure the understanding of the training conducted to employees and as part of assessment check to ensure employees comprehend the SOPs related to their job function, Training and Development performs a quarter evaluation of the training system via verification of employee training records, and via review of quality system records such as but not limited to incidents, non-conformances, deviations, laboratory incidents, laboratory out of specifications, laboratory out of trends, CAPAs, and documentation errors with the purpose of identifying unwanted trends including repetitive human errors that may have been contributed due to lack of training understanding. The findings of this evaluation are discussed with supervisors and management to determine improvement plans for the specific employee in case a negative tendency is observed. The improvement plan, when needed, is designed between supervisor, employee, and Training and Development and executed accordingly to enhance the performance of personnel.

## 7.0 REVISION HISTORY

| Revision No. | Effective Date | Description of Changes |
|---|---|---|
| 01 | SEP 22 2017 | Original SOP |
| 02 | FEB 14 2018 | 1. Add a note for training record associated with training curriculums and qualification techniques under Sections 6.1.1 and 6.3.1.1.4<br>2. Update procedure of completion of training record in Sections 6.2.1.2.2 and 6.2.1.2.3<br>3. Add a note for preparation of training folder by employee under Sections 6.2.2.2 and 6.4.6<br>4. Remove statement related to training not required for other documents in Section 6.2.4.1<br>5. Update on the job training procedure after Section 6.3.3.4<br>6. Update re-certification frequency for qualification techniques in Section 6.4.4<br>7. Make editorial corrections throughout the whole document |

| SOP No. | Title | Revision No. |
|---|---|---|
| ITD-001 | TRAINING SYSTEM | 04 |

| Revision No. | Effective Date | Description of Changes |
|---|---|---|
| 03 | MAR 19 2019 | 1.To mention qualification techniques into sections 1.0 and 3.0.<br>2. To update section 4.0 to include Training Curriculums TC-IGN-001, TC-IGN-002, and TC-IGN-003.<br>3. To add section 6.1.1.1.8 to mention that Acknowledgement of Training Understanding is not applicable for Form ITD-001-F1.<br>4. To remove section 6.1.2 and move the content to section 6.5 as section 6.5.1.<br>5. To update and combine section 6.2.1.2 and 6.2.1.3 to explain training and final release process as part of Training Curriculum TC-IGN-001.<br>6. To add section 6.2.2.3 to include acknowledgement of completion of training curriculum.<br>7. To Modify section 6.2.3 to explain the process of Annual Training as part of Training Curriculum TC-IGN-002.<br>8. To add section 6.3.1.2 to explain self training evaluation process.<br>9. To add a point on section d) of section 6.3.3.2 to mention completion of qualification technique verification.<br>10. To update section 6.4.4 to explain acknowledgment of completion of training for the qualification technique unit operation / module and qualification technique re-certification for visual inspection of Injections.<br>11. To update the "Notes" section on section 6.4 to mention qualification technique matrix, training folders, and qualification technique impact assessment.<br>12. To add section 6.5 to explain evaluation of training. |
| 04 | JUL 2 7 2022 | 1. Add qualification techniques in the Reference Section 4.0<br>2. Add 21 CFR Part 4, WHO Guidelines – Hormones, FDA Guidance – 503B, DBPR, DOH, internal audits, warning letters, and annual trend of 483s under Sections 6.2.1 New Employee Orientation and 6.2.3 Annual Training.<br>3. Add notes under Section 6.2.2 Biennial Training (Continuing Training Program) related to preparation, issuance, and tracking of training curriculums.<br>4. Add notes under Section 6.4 related to qualification techniques to explain the issuance tracking and completion of the qualification technique for initial and recertification purposes.<br>5. Remove Section 6.4.6 from Revision 03.<br>6. Editorial changes made throughout the entire procedure. |

| SOP No. | Title | Revision No. |
|---|---|---|
| IQC-002 | STABILITY PROGRAM | 05 |

| Prepared By / Date | Reviewed By / Date | QA Approved By / Date | Effective Date |
|---|---|---|---|
| Vineda 03/03/21 | 03-05-21 | M. Salazar 03/05/21 | MAR 1 1 2021 |
| | | | Change Control No. |
| Title: QC chemist | Title: Manager, QC | Title: CQCO | I-21090 |

## 1.0 PURPOSE

To establish a standard operating procedure that describes about the stability studies conducted at long term, accelerated, and intermediate storage conditions to establish the shelf life and labeled storage conditions of drug products and medical devices.

## 2.0 SCOPE

This procedure is applicable to drug products and medical devices manufactured by BPI Labs.

## 3.0 RESPONSIBILITY

3.1 Product Development designee is responsible to initiate the stability studies for R&D products.

3.2 Quality Assurance designee is responsible to initiate the stability studies for commercial products.

3.3 Quality Assurance and Quality Control management are responsible for proper implementation of this SOP.

## 4.0 REFERENCES

4.1 FDA Guidelines for Submitting Documentation for the Stability of Human Drugs and Biologics (1987)

4.2 FDA Guidance for industry Q1A (R2) Stability Testing of New Drug Substance and Products

4.3 FDA Guidance for Industry ANDAs: Stability Testing of Drug Substances and Products

4.4 ICH Guidance Q1A (R2) Stability Testing of New Drug Substances and Products

4.5 ICH Guidance Q1B Photostability Testing of New Drug Substances and Products

4.6 ICH Guidance Q1C Stability Testing for New Dosage Forms

4.7 ICH Guidance Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products

4.8 ICH Guidance Q1E Evaluation of Stability Data

4.9 Current USP

4.10 21 CFR 211.166 Stability Testing

4.11 Stability Protocol

4.12 SOP IQA-001 Change Control System

4.13 SOP IQC-001 Investigating Out of Specification (OOS) and Out of Trend (OOT) Test Results

4.14 SOP IQC-003 Standard Procedure for Sample Management in Analytical Development and Quality Control Department

4.15 SOP IGN-030 Operation of the Building Management System

4.16 Form IQA-006-F4 Initiation of Stability Study

4.17 Form IQC-002-F1 Discontinuation of Stability Study Form

4.18 Form IGN-030-F1 Security Monitoring of Environment Controlled Chambers

## 5.0 ATTACHMENTS

Not Applicable.

## 6.0 PROCEDURE

6.1 Definitions / Acronyms:

6.1.1 Stability:

The capacity of a drug product to remain within specifications established to ensure its identity, strength, quality, and purity.

6.1.2 Accelerated Testing:

Studies designed to increase the rate of chemical degradation or physical change of a drug substance or a drug product by using exaggerated storage conditions as part of the formal stability studies.

6.1.3 Long-term Testing:

Stability studies under the recommended storage condition for the retest period or shelf life proposed (or approved) for labeling.

6.1.4 Intermediate Testing:

If any "Significant Changes" occur at any time during testing at the accelerated storage condition, additional testing at the intermediate storage condition should be conducted.

6.2 Materials and Equipment:

6.2.1 Chambers or Walk-in Stability Room:

6.2.1.1 Controlled Room Temperature (CRT) / Long-term:

Environmental chamber / Walk-in Stability Room capable of controlling temperature to 25°C ± 2°C and relative humidity to 60%RH ± 5%RH.

6.2.1.2 Accelerated (AA):

Environmental chamber capable of controlling temperature to 40°C ± 2°C and relative humidity to 75%RH ± 5%RH.

6.2.1.3 Intermediate:

Environmental chamber capable of controlling temperature to 30°C ± 2°C and relative humidity to 65%RH ± 5%RH.

6.2.1.4 Refrigerator:

Environmental chamber capable of controlling temperature to 5 °C ± 3 °C.

6.2.2 Quality Assurance department shall arrange to calibrate the chambers / monitoring devices either in-house or coordinate with the external calibration consultants. Calibrate all the chambers every year.

6.3 Monitoring:

6.3.1 The actual temperature and relative humidity for all chambers and walk-in stability rooms will be monitored and recorded by Quality Assurance Department and Quality Control Department.

6.3.2 All monitoring devices (prints / charts / graphs) will be read and reviewed on a daily basis (business days) by the Quality Assurance Department.

6.3.3 The Quality Assurance Department shall inform to Quality Control Department whenever the temperature and relative humidity reading exceeds out of the temperature and relative humidity tolerances of ± 2°C and / or ± 5%RH, respectively.

6.3.4 All the chambers and walk-in stability rooms are connected to the Security System. This system sends a notification to Security System Operator in case any temperature and relative humidity reading exceeds out of the temperature and relative humidity tolerances of ± 2°C and / or ± 5%RH, respectively. The Security System Operator informs to concerned persons at BPI Labs immediately.

6.3.5 The Security monitoring system of Stability Chambers / Walk-in Stability Room is checked once in every six months by maintenance department in coordination with Security System Company.

6.3.6 After checking the Security monitoring system, details are entered in Form IGN-030-F1 Security Monitoring of Environment Controlled Chambers by maintenance department. The form is submitted to QA for final approval and filing.

6.4 Excursions:

6.4.1 Short term spikes due to opening of doors are acceptable as unavoidable.

6.4.2 If for any reason (e.g., power, equipment failures, etc.), chamber / walk-in stability room is in excursion that exceeds the defined tolerances for more than 24 hours, samples in the chamber / walk-in stability room shall be transferred into back-up chamber. If back-up chamber / walk-in stability room is not available, samples shall be stored at room temperature maximum up to three working days. Once the chamber / walk-in stability room is ready, the samples shall be moved to the original stability condition. If exceeds three working days, the pulling date shall be extended for Accelerated and Intermediate conditions. For CRT condition, it is not required to extend the pulling dates. The impact of such excursion will be assessed.

6.5 Storage Conditions (General Case):

6.5.1 Accelerated Stability (AA):

Samples are stored at 40°C ± 2°C and 75% RH ± 5% RH for a period of six (6) months (i.e., 180 days) for ANDA / ANADA / NDA / NADA. Test intervals are set at 1 month, 2 months, 3 months, and 6 months (i.e.,180 days).

6.5.2 Intermediate Stability (INT):

Samples are stored at 30°C ± 2°C and 65% RH ± 5% RH for a period of twelve (12) months for ANDA / ANADA / NDA / NADA. Test intervals are set at 1 month, 2 months, 3 months, 6 months (i.e.,180 days), 9 months, and 12 months.

6.5.3 Where "significant change" occurs in the samples of accelerated storage conditions, additional testing at the intermediate storage conditions (i.e., 30°C ± 2°C and 65% RH ± 5% RH) shall be conducted.

6.5.3.1 "Significant Change" at the accelerated condition is defined as:

A. A 5% potency loss from the initial assay value of a batch.

B. Any specified degradant exceeding its specification limit.

C. Dissolution exceeding the specification limits for 12 Dosage units (USP Stage 2).

D. Failure to meet specifications for appearance and physical properties.

E. Failure to meet the acceptance criterion for pH.

6.5.4 Long-term Stability (CRT):

Samples are stored at 25°C ± 2°C and 60% RH ± 5% RH (controlled room temperature) for up to shelf life for ANDA / ANADA and may be longer for NDA / NADA. Test intervals are at 3 months, 6 months (i.e., 180 days), 9 months, 12 months, 18 months, 24 months, and on an annual basis up to the proposed shelf life for NDA / NADA / ANDA / ANADA. Additional intervals can be assigned on a case-by-case basis.

6.6 Storage Conditions (Drug Product Intended for Storage in a Refrigerator):

6.6.1 Accelerated Stability (AA):

Samples are stored at 25°C ± 2°C and 60% RH ± 5% RH for a period of six (6) months for ANDA / ANADA / NDA / NADA. Test intervals are set at 1 month, 2 months, 3 months, and 6 months (i.e.,180 days).

6.6.2 Long-term Stability:

Samples are stored at 5°C ± 3°C in a refrigerator for a period of twelve (12) months for ANDA / ANADA / NDA / NADA. Test intervals are set at 3 months, 6 months (i.e.,180 days), 9 months, 12 months, 18 months and 24 months. Additional intervals can be assigned on a case-by-case basis.

6.7 Storage Conditions (Drug Product Intended for Storage in a Freezer):

6.7.1 Long-term Stability:

Samples are stored at - 20°C ± 5°C in a freezer for a period of twelve (12) months for ANDA / ANADA / NDA / NADA. Test intervals are set at 3 months, 6 months (i.e.,180 days), 9 months, 12

months, 18 months and 24 months. Additional intervals can be assigned on a case-by-case basis.

6.7.2 Testing on a single batch at an elevated temperature (e.g., 5°C ± 3°C or 25°C ± 2°C) for an appropriate time period should be conducted to address the effect of short-term excursions outside the proposed label storage condition.

6.8 Storage Conditions (Drug Product Intended for Storage Below - 20°C):

6.8.1 Drug products intended for storage below - 20°C should be treated on a case-by-case basis.

**NOTE: If a drug product is required to be stored at condition different from above mentioned storage conditions, a separate stability protocol will be initiated that will contain all the critical information such as storage condition, test intervals, etc.**

6.9 Preparation of Stability Protocol:

6.9.1 Stability protocols shall be prepared by Product Development for R&D products and by Quality Assurance for commercial products before the stability study is initiated.

6.9.2 Stability protocols shall include all specific details of the product and stability study such as, but not limited to, product name and strength, code number, active pharmaceutical ingredient associated, batch size, pack size and packaging configuration, study purpose, storage conditions, testing frequency, tests, number of containers to be pulled per sampling point, and number of samples to be collected.

6.9.3 Bracketing and Matrixing designs for stability testing of drug products can be applied according to ICH Guidance Q1D: Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products.

6.9.4 Stability protocols are approved in the quality system via change control following instructions documented in SOP IQA-001.

6.10 Initiation of Stability Study:

6.10.1 Stability study for R&D products is initiated by Product Development Department using the approved stability protocol. Stability samples are collected by Quality Assurance and submitted to Quality Control accordingly.

6.10.2 Stability study for commercial products (including validation) is initiated by Quality Assurance Department using the approved stability protocol and Form IQA-006-F4 (Initiation of Stability Study). Stability samples are collected by Quality Assurance and submitted to Quality Control accordingly.

6.10.3 Upon receipt, Quality Control Department verifies stability samples for correctness and integrity and ensures that an approved stability protocol associated with this stability study is available and that information documented in the protocol or Form IQA-006-F4 is accurate.

6.10.4 The stability samples shall be labelled as Upright (U), Inverted (I) and On the Side (OTS) orientations on the cartons as per stability protocol and the samples shall be loaded carefully into chambers as per orientation.

6.11 Scheduling:

6.11.1 The stability system scheduling shall be documented in stability protocol (i.e., R&D products) or using Form IQA-006-F4 (i.e., commercial products) upon initiations of any new stability studies for the products.

6.11.2 When the stability samples are loaded into the stability chamber, stability group or designee shall enter the initiating information into the stability logbook.

6.11.3 Stability samples (i.e., exhibit batches) can be loaded into the stability chambers after packaging without waiting for the release of time zero data to save the stability study time.

6.12 Sample Retrieval:

6.12.1 A monthly calendar with the products to be tested for that month will be generated from the Excel sheet / Microsoft outlook according to the approved stability protocol or Form IQA-006-F4.

6.12.2 The Stability Coordinator or designee will remove the appropriate quantity of samples according to stability protocol or Form IQA-006-F4 from storage, document such retrieval in the respective stability protocol or Form IQA-006-F4, and submit stability samples to the laboratory for testing.

6.12.3 When the stability samples are retrieved from the stability chamber, stability group or designee shall reflect this activity in the stability logbook.

6.12.4 The samples will be logged in the Stability Samples Logbook in Quality Control Department as per SOP IQC-003.

**NOTE: Ensure to submit samples required for Microbiology testing (as per stability protocol) on the same day of retrieval (if applicable).**

6.12.5 For pull dates, which fall on non-working days, samples will be pulled on the next working day.

6.13 Testing:

6.13.1 Samples will be tested in accordance with approved Stability Protocol using approved test methods, which are specific, and stability indicating.

6.13.2 For testing, sampling of dosage units from a given container should be done randomly with each individual unit having an equal chance to be selected. The chemist must inspect samples before testing and report any untoward appearance / findings to their supervisor or manager.

6.13.3 Accelerated and intermediate storage conditions samples testing should be completed within 15 calendar days of retrieval.

**NOTE: In case of Microbiology testing, testing must be completed within 30 calendar days (excluding weekends / holidays) of retrieval.**

6.13.4 Long term storage conditions samples testing should be completed within 15 working days.

**NOTE: In case of Microbiology testing, testing must be completed within 30 calendar days (excluding weekends / holidays) of retrieval.**

6.13.5 If testing is delayed, then the reasons and the impact for the delays shall be clearly documented and approved by the responsible Quality Control Manager or designee and submitted to Quality Assurance Department along with the stability data report.

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6.14 Recording Results:

6.14.1 Results of testing are recorded as they are completed and checked against any previous data by group auditor or designee.

6.14.2 Test result failures shall be brought to the immediate attention of the Quality Control Manager or designee who shall notify the Quality Assurance Management consequently. Investigation of out of specifications or out of trends shall be conducted according to SOP IQC-001.

6.14.3 The SOP IQC-001 Investigating Out of Specification (OOS) and Out of Trend (OOT) Test Results, is not applicable for RLD and Experimental drug products.

6.15 Analysis Reporting Data:

6.15.1 Stability reports will be reported using product approved specification and analytical reports and according to stability data compilation sheets included in the stability protocol and will be submitted to Quality Assurance for review. The data should be submitted within 40 calendar days.

6.15.2 Stability reports will be provided to Regulatory Affairs for annual reports and other FDA submissions, as needed.

6.16 Documentation:

6.16.1 A stability project file will be maintained for each product initiated into the program.

6.16.2 Quality Control Manager or designee will ensure the current finished product specification is used for reporting purposes.

6.16.3 Initial release test results (time zero data) need to be available for all samples.

6.16.4 If more than 30 days have passed since the initial release date, stability initiator must submit additional samples for retest.

6.16.5 The Stability Chamber Logbooks as well as documentation included in the stability protocol or Form IQA-006-F4 will serve as documentation of the stability samples pulls.

6.17 Transportation of Stability Samples:

6.17.1 The Quality Control Manager or designee sending stability samples should ensure that the samples transported for loading into the stability chambers of any subsidiary or third party are transported as per the label storage conditions.

6.17.2 If there is any damage to the integrity of the container closure system of the sample during transit, the sample will not be loaded in the stability chambers.

6.17.3 The stability samples received for only loading into the stability chambers need to follow the stability conditions provided along with the samples.

6.18 Post-approval Stability Commitment:

6.18.1 If the submission does not include stability data on production batches, a commitment should be written in a specific stability protocol.

6.18.2 The stability protocol used for the studies on commitment batches should be the same as that for the primary batches, unless otherwise scientifically justified.

6.18.3 The commitment shall include the stability studies at intended long term storage conditions (at 25°C ± 2°C / 60% RH ± 5% RH) on the first three production batches in each packaging size.

6.18.4 In addition to the first three production batches, stability studies at 25°C ± 2°C / 60% RH ± 5% RH will be conducted on a minimum of one production batch per year for each packaging size.

6.18.5 The stability results for the drug product shall be reported in the annual report of the ANDA.

6.19 Changes or Cancellations:

6.19.1 Any change or termination of stability testing must be submitted in writing to the Quality Assurance Management with a completed Discontinuation of Stability Study Form (IQC-002-F1) in the stability Protocol. The stability system shall be updated immediately.

## 7.0 REVISION HISTORY

| Revision No. | Effective Date | Description of Changes |
|---|---|---|
| 01 | JAN 10 2018 | Original SOP |
| 02 | AUG 12 2019 | 1.Alignment was updated.<br>2.Added a note following point 6.12.4 detailing samples for microbiology laboratory must be submitted on same day of retrieval.<br>3.Added a note following point 6.13.3 and 6.13.4 describing microbiology testing must be completed in 30 working days. |
| 03 | NOV 22 2019 | 1. Changed 6.5.3.1 from "12 capsules or tablets" to "12 Dosage units"<br>2. Added 6.2.1.4 Refrigerator and its condition temperature.<br>3. Added Subsection E in section 6.5.3.1 |
| 04 | SEP 29 2020 | 1. Added section 6.10.4 for introducing orientation of stability samples<br>2. Editorial changes were made throughout the SOP wherever applicable |
| 05 | MAR 1 1 2021 | 1.Removed the form IQC-002-F2 form sections 4.0 and 6.3.6 and added the form IGN-030-F1.<br>2.Added the SOP#IGN-030 and Form# IGN-030-F1 in the references section |

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| Prepared By / Date | Reviewed By / Date | QA Approved By / Date | Effective Date |
|---|---|---|---|
| Sabrina Iannucci 10/18/22 | 10/18/22 | M. Salazar 10/18/22 | OCT 20 2022 |
| Title: Process Engineer | Title: Director, Tech Ops | Title: CQCO | Change Control No. I-22608 |

## 1.0 PURPOSE

The purpose of this procedure is to provide standard operating instructions for the visual inspection of injections.

## 2.0 SCOPE

This procedure is applicable to personnel performing visual inspection of injections at BPI Labs facility, Suite #450.

## 3.0 RESPONSIBILITY

3.1 It is the responsibility of personnel performing visual inspection of injections to follow these instructions. It is also the responsibility of the Production Supervisor to implement and ensure that the procedure is being followed.

3.2 It is the responsibility of Production (PD) department and Production Supervisor to compile visual inspection results for trending. It is the responsibility of Quality Assurance (QA) department to prepare trending report.

## 4.0 REFERENCES

4.1 General Chapters USP <790> Visible Particulates in Injections

4.2 General Chapters USP <1790> Visual Inspection of Injections

4.3 USFDA Guidance for Industry Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice

4.4 PDA Survey 2014 Visual Inspection

4.5 PDA Survey 2015 Particulate Matter in Difficult to Inspect Parenterals

4.6 Technical Report No. 43 (Revised 2013) Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing: Covering Ampoules, Bottles, Cartridges, Syringes and Vials

4.7 SOP IGN-001 Investigations

4.8 SOP IGN-020 Procedure for Repair and Maintenance of Equipment / Rooms

4.9 SOP IGN-024 Waste Disposal Authorization

4.10 SOP IMI-038 Determination of Particulate within Injectables Products using Filtration Method

4.11 SOP IPD-017 Qualification and Validation of Inspection Processes

4.12 SOP IPK-003 Brite Stock Handling

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4.13 SOP IQA-006 Issuance of Batch Records, Packaging Records, Protocols, and In-House Computer Generated Labels

4.14 SOP IQA-016 Acceptable Quality Limit for Visual Inspection of Filled Product

4.15 SOP IWH-004 Storage and Disposal of Manufacturing and Laboratory Waste

4.16 Form IGN-001-F1 Investigation Report

4.17 Form IGN-024-F1 Waste Disposal Authorization Form

4.18 Form IPD-007-F1 Visual Inspection of Injections Report

4.19 Form IPD-007-F2 Visual Inspection Booth Light Intensity Verification Form

4.20 Form IPD-007-F3 Log for Visual Inspection of Injections

4.21 Form IQA-016-F1 Acceptable Quality Limit for Visual Inspection of Filled Product Report

4.22 IQA-016-F2 American National Standard (ANSI Z1.4) Sampling Plan

4.23 Respective Product Validated List (i.e., EOL I-034)

## 5.0 ATTACHMENTS

Not Applicable.

## 6.0 PROCEDURE

6.1 General:

6.1.1 In general, unless specified in the manufacturing batch record, Visual Inspection is performed for all cGMP Products. The inspection program is designed to understand the nature of defects and establish appropriate controls to eliminate them based on the product life cycle.

6.1.2 Personnel participating in Visual Inspection of Injections must be trained and qualified as per SOP IPD-017 Qualification and Validation of Inspection Processes.

6.1.3 Inspectors must have their eyes examined by an optometrist at least once a year as per specifications listed in SOP IPD-017. The frequency may be increased if the inspectors complain of headache, eye fatigue, or other complaints directly attributable to visual performance.

6.1.4 Supervisors must be informed if any inspectors are suffering from eye allergies, eye infections, eye fatigue, headache, or any other concerns that affect the performance of inspection.

6.1.5 Inspectors must gown with hair net, beard cover (if facial hair is present), lab coat, and gloves when entering the visual inspection room. Inspectors must degown within respective visual inspection room prior to exiting.

6.1.5.1 Gowning materials such as lab coat must be dedicated to a single batch. If inspections are performed in multiple rooms then separate gowning materials are required.

6.1.6 Avoid glare and direct viewing of the light source at high intensities as this may result in eye strain or fatigue.

6.1.7 Check the intensity of light before the start of a batch and after completion of each batch.

6.1.8 After every 55-65 minutes of visual inspection, a no less than 5-minute break MUST be taken to relax eyes. Document inspection and break times in Form IPD-007-F1 section II.

6.1.8.1 When a break is required, the inspector should finish the tub or tray they are inspecting before taking a break. If they are unable to finish, they must keep inspected and uninspected units separate and secure before taking a break and upon returning, must start with the same uninspected tub/tray.

6.1.8.2 The inspection times and break times should be sequential. For example, an inspector inspects on 07/24/19 from 11:00 to 12:03 and he/she takes a break from 12:03 to 12:08. This will be documented on one line, from left to right, in section II of IPD-007-F1 and initialed by the inspector.

6.1.8.3 All open entries in section II of form IPD-007-F1 should be closed on the same day of completion.

6.1.9 Visual inspection rooms must be locked if visual inspection personnel are not in the room. Visual inspection personnel are responsible for locking the visual inspection room door during breaks and at end of business day.

6.1.10 Visual inspectors are not required to use a magnifier or wear safety glasses during the inspection. Magnification should only be used for critical examination of a small number of units, as may be needed during an investigation. The use of the magnifier will be determined by a supervisor or designee.

6.1.11 There are three different categories of defects representing the risk to the patient, as defined below.

6.1.11.1 Critical Defect:

A defect which poses risk to the patient, especially risk of injury to patient and integrity breach of container closure (sterility of the product) and indicates the inspected article is likely to:

A. Result in hazardous or unsafe conditions for individuals using, maintaining, or relying on the product; or

B. May prevent performance of the product or material or failure to meet specifications. A critical defect is a unit of product that contains one or more critical defects.

Examples: Critical defects include cracks in the glass of the vial or syringe, missing stopper/plunger, etc.

6.1.11.2 Major Defect:

A condition/non-conformity, other than critical, that carries the risk of a temporary impairment or medically reversible reaction or involves a remote probability of a serious adverse reaction or reduce the usability of the unit of product for its intended purpose. A major defect is a unit of product that contains one or more major defects.

Examples: Major defects include contamination intrinsic to the manufacturing process such as fibers or particles and issues associated with the filling/stoppering process such as low fill, high fill, or empty container.

6.1.11.3 Minor Defect:

A minor defect is a condition/non-conformity that is not likely to reduce the usability of the unit of product for its intended purpose or is a departure from established standards having little bearing on the effective use, safety or operation of the unit of product. A minor defect is a unit of product that contains one or more defects. They are often cosmetic in nature, affecting only product appearance or pharmaceutical elegance.

Examples: Minor defects include cosmetic issues such as scratches/scuffs on the body of the vial/syringe, dents on the container/cap, etc.

6.2 Handling of the Visual Inspection Booths:

6.2.1 Setup:

6.2.1.1 Setup inspection booth on the workbench for safe and comfortable operation.

6.2.1.2 Connect to 120 Volts power source and turn ON the light switch and ensure lights are illuminating with no flickering. If the lights do not function properly, contact area supervisor and initiate a maintenance request as per SOP IGN-020.

6.2.2 Operation:

6.2.2.1 Log equipment usage into appropriate Cleaning, Use, and Maintenance Logbook.

6.2.2.2 Ensure the light is turned on and verify in the appropriate logbook that the Visual Inspection Booth is cleaned prior to use. If not, follow step 6.2.3 as applicable.

6.2.2.3 When inspecting filled product, hold the units approximately 8-10 inches below the light source and NMT 5 inches from the center line.

6.2.2.4 When finished with operation, ensure the light is turned off.

6.2.3 Cleaning:

6.2.3.1 Minor Cleaning:

A. Ensure the power is turned OFF.

B. Remove all evidence of the previous batch, including all filled product, both inspected and rejected.

C. Wipe down the interior of the inspection booth with 70% Isopropyl Alcohol (IPA).

D. Record the activities into the proper Cleaning, Use, and Maintenance logbook and ensure the cleaning is verified by a Supervisor or designee.

E. Place a "CLEAN" label on the Visual Inspection Booth

6.2.3.2 Major Cleaning:

A. Ensure the power is turned OFF.

B. Remove all evidence of the previous batch, including all filled product, both inspected and rejected.

C. Wipe down the interior and exterior of the inspection booth and the magnifying glass with a lint-free cloth and 70% IPA.

D. Record the activities into the proper Cleaning, Use, and Maintenance logbook and ensure the cleaning is verified by a Supervisor or designee.

E. Place a "CLEAN" label on the Visual Inspection Booth.

6.2.4 Verification of Light Intensity:

6.2.4.1 Light intensity verification will be performed annually for all Visual Inspection Booths using NIST calibrated standard Light Intensity Meter. Measure the light intensities at the locations specified in Form IPD-007-F2 and record values in Form.

6.2.4.2 Light intensity should be NLT 2100 lux at the furthest specified point. If the light intensity fails to meet the acceptance criteria, initiate a maintenance request as per SOP IGN-020 and repeat verification after maintenance is performed.

6.2.5 Corrective Maintenance:

6.2.5.1 In case of equipment break down, contact maintenance personnel for necessary actions. Refer to SOP IGN-020 for repair/maintenance procedure.

6.3 Visual Inspection Requirements per Product Type:

6.3.1 Manual visual inspection requirements are based on product type. Refer to Table 1 for inspection requirements per batch type and corresponding procedure section.

**Table 1: General Visual Inspection Requirements Based on Product Type**

| Product Type | Inspection Requirement | Procedure Section |
|---|---|---|
| Research and Development (Exhibit / Stability / Pivotal) | 100% Inspection (One Time) | 6.4 |
| Initial Commercial (i.e., Initial Process Validation) | First and Second 100% Inspections (Two Times) | 6.5 |
| Commercial Certified for Reduced Inspection | 100% Inspection (One Time) | 6.7 |
| Difficult to Inspect (i.e., Colored Products for Research and Development & Commercial) | 100% Inspection (One Time)<br>Destructive Testing | 6.8 |

6.3.1.1 Research and Development products (Exhibit / Stability / Pivotal) are one time 100% inspected by Production personnel.

6.3.1.2 Initial Commercial products (if not qualified under reduced inspection program) are two times (First 100% and Second 100%) inspected by Production personnel. Although regulatory expectations require only 100% inspection, Second 100% inspection is

performed to better understand the life cycle of the product, common defects types, and provide product quality assurance.

6.3.1.3 Commercial products certified for the Reduced Inspection Certification Program are one time 100% inspected by Production personnel. To determine if the product is qualified for reduced inspection program, refer to the respective Product Validated List (i.e., EOL I-034).

6.3.1.4 Difficult to inspect products (i.e., colored products for Research and Development & Commercial) are one time 100% inspected by Production personnel and then tested as per supplemental destructive testing.

**NOTE: Whenever samples are required to be submitted to Quality Control and Microbiology for testing prior to the completion of visual inspection of the entire batch, visual inspection can be performed on representative tub or tray of filled units from beginning, middle, and end of the run using the appropriate procedure. Record inspection of such selected tub or tray using form IPD-007-F1, i.e., if a batch has 100 tub or tray, 10,000 units are filled (100 units per tub or tray), and 45 units of samples are required for Quality Control and Microbiology testing, select tub or tray 1, 50, and 100 for the inspection. Upon completion of the inspection of all units in the three tubs or trays, notify QA to collect representative samples as per SOP IQA-007.**

6.3.2 Production department requests visual inspection forms with Batch Manufacturing Record using Form IQA-006-F1 "Batch / Packaging Record Request Form". Production department will verify the visual inspection requirements (either First 100% and Second 100% inspections or only First 100% inspection) using the respective Product Validated List (i.e., EOL I-034) to determine the amount of visual inspection forms needed.

6.3.3 Form IPD-007-F1 "Visual Inspection of Injections Report" is issued for each individual involved in visual inspection. Form IPD-007-F3 "Log for Visual Inspection of Injections" is issued per batch. These forms are issued with the Batch Manufacturing Record by QA department.

## 6.4 Inspection of Research and Development Products:

6.4.1.1 Research and Development (Exhibit / Stability / Pivotal) products are one time 100% inspected by Production personnel. Refer to Figure 1 for a general overview of research and development product inspections.

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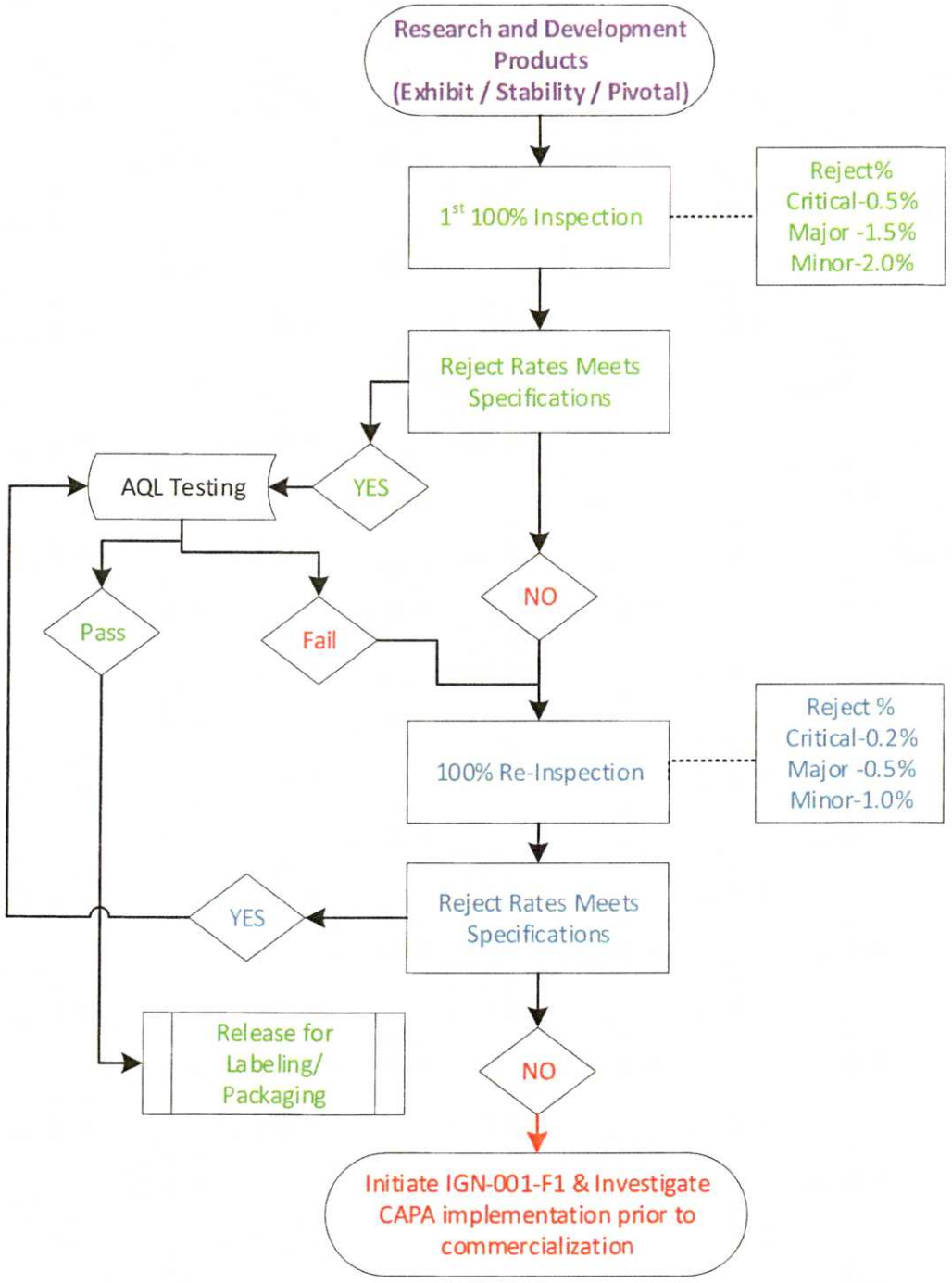



**Figure 1: General Visual Inspection Process for Research and Development Products**

6.4.1.2 Before QA issues line clearance, ensure the product is secured (e.g., cage with fastener and lock, rack that has been wrapped) and there is no sign of tampering. If there is evidence of tampering, notify supervisor or designee immediately to determine how to proceed.

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6.4.1.3 Once line clearance has been given, bring product into the room and place a STATUS label on the rack/cage containing filled product (Status should be: To Be Inspected).

6.4.1.4 Place a STATUS label on the receiving rack/cage with appropriate status (e.g., First 100% inspected product, 100% re-inspected product)

6.4.1.5 Test light intensity using NIST calibrated standard Lux Meter prior to inspection start, and record results in Form IPD-007-F1. Light intensity should be NLT 2100 lux approximately 8-10 inches from the light source. If the light intensity is less than 2100 lux the booth cannot be used for inspection, initiate a maintenance request as per SOP IGN-020.

6.4.1.6 Collect one Filled Units tub/tray to be inspected at a time from the batch of filled units. If filled units are in tubs count the number of units available for inspection and record number of units in the appropriate space on form IPD-007-F1 and check the First 100% inspection box. If filled units are in trays, prepare another empty tray to place inspected units.

6.4.1.7 Pick up and hold the units in between finger and thumb in horizontal position (with bottom of the vial/syringe touching the thumb) approximately 8-10 inches below the light source and NMT 5 inches from the center line. Rotate and observe the containers, slowly, for five seconds in such a way that the complete body of the containers, including neck and bottom, are visible for inspection. Observe the containers for following defects:

A. For inspection of vials with Liquid Product:

a. Scratches/Scuff Marks on Body
b. Dents on Container
c. Dents on Flip-cap
d. Dirt on Exterior Surface
e. Empty Container
f. Cracked vial
g. Leakage
h. Missing Stopper
i. Missing Flip-cap
j. Incomplete seal/cap
k. Wrong color stopper/cap
l. Crimp defect (loose crimp or non-uniform crimp)

**NOTE: When inspecting for incomplete seal/cap, rotate unit between fingers and ensure the cap is leveled with the vial and the seal is securely locked from all points. Holding in one hand, move the cap head side to side and ensure the securing flanges do not move past the crown of the vial.**

B. For inspection of syringes with Liquid Product:

a. Scratches/Scuff Marks on Body
b. Dents on Container
c. Dents on needle sheath or luer lock
d. Dirt on Exterior Surface
e. Empty syringe
f. Cracked or broken syringes
g. Missing stopper
h. Wrong stopper position (stopper upside down) with reference to standard
i. Liquid between stopper ribs
j. Partially Inserted Stopper, with reference to standard

6.4.1.8 Gently swirl or invert the vials/syringes making sure that minimal air bubbles are introduced and bring back to an upright position. Inspect the product in front of the **black background** for minimum five seconds and check for the defects mentioned below, as applicable for vials or syringes with liquid product.

A. For inspection of Liquid Product in either vials or syringes:

a. Low Fill Level
b. High Fill Level
c. Discolored, or Cloudy/Precipitate
d. Colored particles
e. Black Particles
f. White Particles
g. Glass Particles
h. Fibers

6.4.1.9 Invert the vials/syringes momentarily and bring to an upright position and inspect the product in front of the **white background** for minimum five seconds and check for the defects mentioned below.

A. Black/Brown Particles
B. Fibers
C. Colored Particles

**NOTE: As each unit is inspected in front of black and white background each for a minimum of five seconds, and maximum of 2 containers are inspected at a time, it will take 20 seconds to inspect 2 units. No more than 360 units should be inspected per hour.**

6.4.1.10 Accepted vials/syringes will be placed into their respective tub/tray. Rejected vials/syringes will be marked with the defect code number as listed in IPD-007-F1 form section III and placed into the appropriate labeled reject bin (i.e., critical reject bin, major reject bin, minor reject bin).

**NOTE: If an inspector has a doubt about a defect category, another qualified inspector may inspect and confirm.**

6.4.1.11 At the end of inspection process, test light intensity using NIST calibrated standard Lux Meter, and record in Form IPD-007-F1. Light intensity should be NLT 2100 lux approximately 8-10 inches from the light source; if the light intensity does not meet specification, initiate a maintenance request as per SOP IGN-020. All units inspected in this booth must be re-inspected after taking corrective action/repair or perform inspection in any other inspection booth.

6.4.1.12 Individual operators will reconcile the inspected units and rejects in his/her form and attach to the batch record.

6.4.1.13 Review total reject rates from the First 100% inspection through respective inspection forms. If it is within the specified limits from batch record, coordinate with Quality Assurance for Acceptable Quality Level (AQL) Inspection. If the reject rates are not specified in the Batch Manufacturing Record, follow the limits specified in Table 2.

Table 2: Research and Development Products Visual Inspection Acceptance Criteria

| Type of Defects | % Reject Rates (Action Level) | |
|---|---|---|
| | First 100% Inspection | 100% Re-inspection |
| Critical Defects | 0.5 | 0.2 |
| Major Defects | 1.5 | 0.5 |
| Minor Defects | 2.0 | 1.0 |

A. If the reject rates from the first 100% inspection are NOT within the specified limits, request Quality Assurance Document Control to issue respective Batch record pages and Form IPD-007-F1 for 100% re-inspection as per SOP IQA-006.

B. Review total reject rates from 100% re-inspection. If it is within the specified limits from batch record or Table 2 "**100% Re-inspection**", coordinate with Quality Assurance for Acceptable Quality Level (AQL).

C. If first AQL inspection fails, re-inspection of complete batch is performed with "100% Re-inspection" limits in Table 2. Once re-inspection is complete, a second AQL inspection can be performed with tightened inspection limits, as per SOP IQA-016. If it is NOT within the specified limits, inform supervisor. An investigation must be initiated as per IGN-001, corrective and preventive actions must be implemented prior to commercial batch manufacturing.

6.4.1.14 Once AQL inspection is complete and the batch record has been updated, the filled product can be further released for labeling and packaging.

A. If product is left unattended, ensure the product is secure (e.g., secured in a cage with fastener and lock).

6.4.1.15 If the filled product needs transfer to the warehouse, prepare the transfer by following the procedure in SOP IPK-003.

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## 6.5 Inspection of Initial Commercial Products:

6.5.1.1 Initial Commercial products (i.e., initial process validation batches) are First 100% inspected and then Second 100% inspected, unless they are qualified for Reduced Inspection Program. To determine if the product is qualified for reduced inspection program, refer to the respective Product Validated List (i.e., EOL I-034).

**NOTE: Refer to section 6.7 for Inspection of Commercial Products Certified for Reduced Inspection Program.**

A. Refer to Figure 2 for the general inspection process for initial Commercial batches.

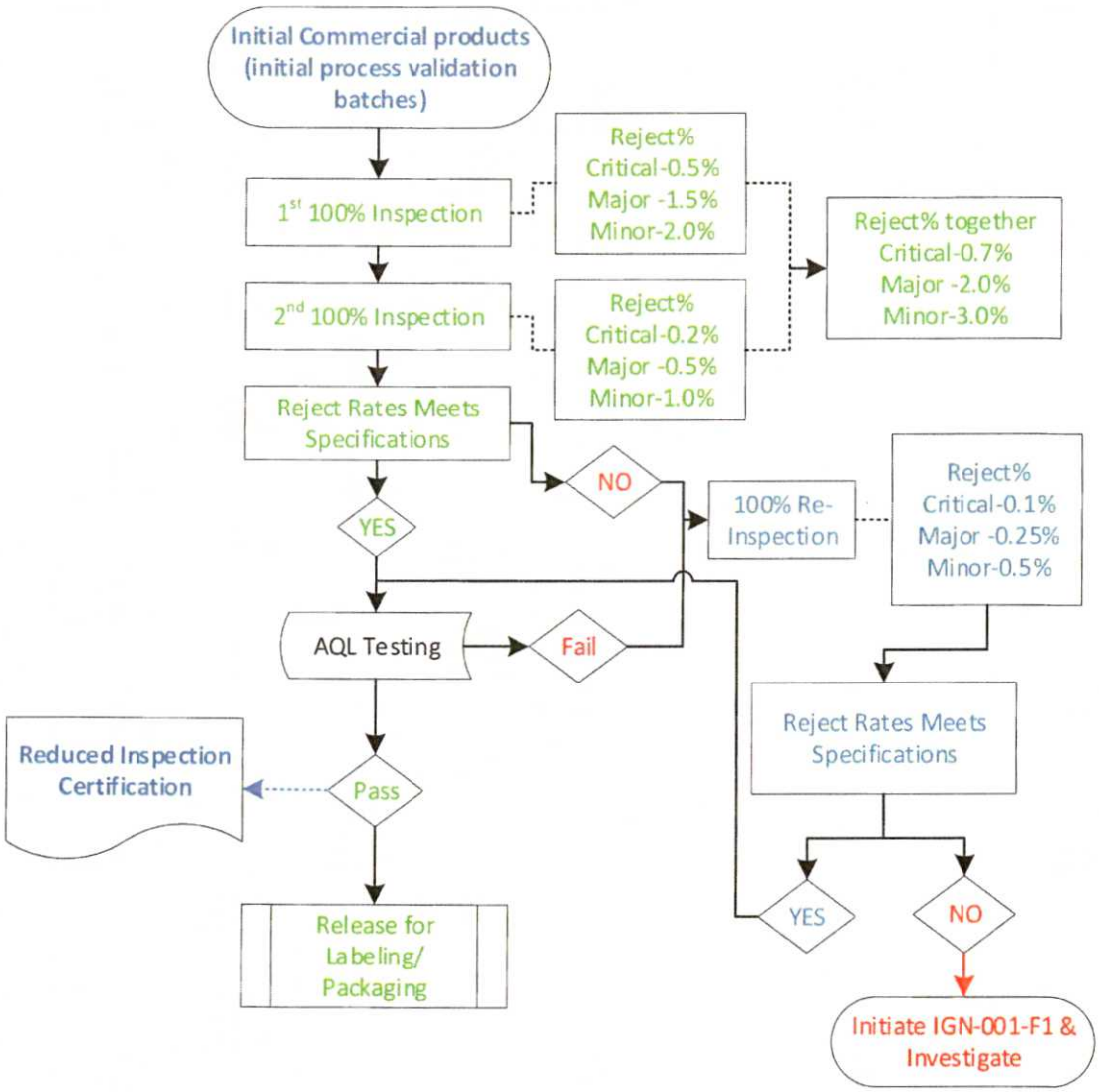



**Figure 2: General Visual Inspection Process for Commercial Batches Prior to Reduced Inspection Certification**

6.5.1.2 Before QA issues line clearance, ensure the product is secured (e.g., cage with fastener and lock, rack that has been wrapped) and there is no sign of tampering. If there is

evidence of tampering, notify supervisor or designee immediately to determine how to proceed.

6.5.1.3 Once line clearance has been given, bring product into the room and place a STATUS label on the rack/cage containing filled product (Status should be: To Be Inspected).

6.5.1.4 Place a STATUS label on the receiving rack/cage with appropriate status (e.g., First 100% inspected product, Second 100% inspected product, 100% re-inspected product)

6.5.1.5 Test light intensity using NIST calibrated standard Lux Meter prior to inspection start, and record results in Form IPD-007-F1. Light intensity should be NLT 2100 lux approximately 8-10 inches from the light source. If the light intensity is less than 2100 lux the booth cannot be used for inspection, initiate a maintenance request as per SOP IGN-020.

6.5.1.6 Collect one Filled Units tub/tray to be inspected at a time from the batch of filled units. If filled units are in tubs count the number of units available for inspection and record number of units in the appropriate space on form IPD-007-F1 and check the First 100% inspection box. If filled units are in trays, prepare another empty tray to place inspected units.

6.5.1.7 Pick up and hold the units in between finger and thumb in horizontal position (with bottom of the vial/syringe touching the thumb) approximately 8-10 inches below the light source and NMT 5 inches from the center line. Rotate and observe the containers, slowly, for five seconds in such a way that the complete body of the containers, including neck and bottom, is visible for inspection. Observe the containers for following defects:

A. For inspection of vials with Liquid Product:

a. Scratches/Scuff Marks on Body
b. Dents on Container
c. Dents on Flip-cap
d. Dirt on Exterior Surface
e. Empty Container
f. Cracked vial
g. Leakage
h. Missing Stopper
i. Missing Flip-cap
j. Incomplete seal/cap
k. Wrong color stopper/cap
l. Crimp defect (loose crimp or non-uniform crimp)

**NOTE: When inspecting for incomplete seal/cap, rotate unit between fingers and ensure the cap is leveled with the vial and the seal is securely locked from all points. Holding in one hand, move the cap head side to side and ensure the securing flanges do not move past the crown of the vial.**

B. For inspection of syringes with Liquid Product:

a. Scratches/Scuff Marks on Body
b. Dents on Container
c. Dents on needle sheath or luer lock
d. Dirt on Exterior Surface
e. Empty syringe
f. Cracked or broken syringes
g. Missing stopper

h. Wrong stopper position (stopper upside down) with reference to standard
i. Liquid between stopper ribs
j. Partially Inserted Stopper, with reference to standard

6.5.1.8 Gently swirl or invert the vials/syringes making sure that minimal air bubbles are introduced and bring back to an upright position. Inspect the product in front of the **black background** for minimum five seconds and check for the defects mentioned below, as applicable for vials or syringes with liquid product.

A. For inspection of Liquid Product in both vials and syringes:

a. Low Fill Level
b. High Fill Level
c. Discolored, or Cloudy/Precipitate
d. Colored particles
e. Black Particles
f. White Particles
g. Glass Particles
h. Fibers

6.5.1.9 Invert the vials/syringes momentarily and bring to an upright position and inspect the product in front of the **white background** for minimum five seconds and check for the defects mentioned below.

A. Black/Brown Particles
B. Fibers
C. Colored Particles

**NOTE: As each unit is inspected in front of black and white background each for a minimum of five seconds, and maximum of 2 containers are inspected at a time, it will take 20 seconds to inspect 2 units. No more than 360 units should be inspected per hour.**

6.5.1.10 Accepted vials/syringes will be placed into their respective tub/tray. Rejected vials/syringes will be marked with the defect code number as listed in IPD-007-F1 form section III and placed into the appropriate labeled reject bin (i.e., critical reject bin, major reject bin, minor reject bin).

**NOTE: If an inspector has a doubt about a defect category, another qualified inspector may inspect and confirm.**

6.5.1.11 At the end of inspection process, test light intensity using NIST calibrated standard Lux Meter, and record in Form IPD-007-F1. Light intensity should be NLT 2100 lux approximately 8-10 inches from the light source; if the light intensity does not meet specification, initiate a maintenance request as per SOP IGN-020. All units inspected in this booth must be re-inspected after taking corrective action/repair or perform inspection in any other inspection booth.

6.5.1.12 Individual operators will reconcile the inspected units and rejects in his/her form and attach to the batch record.

6.5.1.13 Review total reject rates from the first 100% inspection through respective inspection forms, typical "**First 100% Inspection**" % Rejects Rates are listed in Table 3.

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Table 3: Initial Process Validation/Commercial Products Visual Inspection Acceptance Criteria

| Type of Defects | % Reject Rates (Action Level) | | | |
|---|---|---|---|---|
| | First 100% Inspection | Second 100% Inspection | Together First & Second Inspection | 100% Re-inspection |
| Critical Defects | 0.5 | 0.2 | 0.7 | 0.1 |
| Major Defects | 1.5 | 0.5 | 2.0 | 0.25 |
| Minor Defects | 2.0 | 1.0 | 3.0 | 0.5 |

6.5.1.14 Perform a Second 100% inspection following the same procedure as the First 100% inspection, typical "**Second 100% Inspection**" % Rejects Rates are listed in Table 3.

6.5.1.15 Rejected vials/syringes will be marked with the defect code number as listed in IPD-007-F1 form section III and placed into the appropriate labeled reject bin (i.e., critical reject bin, major reject bin, minor reject bin).

6.5.1.16 At the end of inspection process, test light intensity using NIST calibrated standard Lux Meter, and record in Form IPD-007-F1. Light intensity should be NLT 2100 lux approximately 8-10 inches from the light source; if the light intensity does not meet specification, initiate a maintenance request as per SOP IGN-020. All units inspected in this booth must be re-inspected after taking corrective action/repair or perform inspection in any other inspection booth.

6.5.1.17 Individual operators will reconcile the inspected units and rejects in his/her form and attach to the batch record.

6.5.1.18 Once the Second 100% inspection is complete, inform supervisor or designee to summarize overall inspection results in Form IPD-007-F3 and Batch Manufacturing Record.

6.5.1.19 Review total reject rates "**Together First & Second Inspection**" in respective inspection forms. If it is within the specified limits listed in batch record or Table 3, coordinate with Quality Assurance for Acceptable Quality Level (AQL) Inspection.

A. If the reject rates from the "**Together First & Second Inspection**" are NOT within the specified limits, request Quality Assurance Document Control to issue respective Batch record pages and Form IPD-007-F1 for 100% re-inspection as per SOP IQA-006.

B. Review total reject rates from 100% re-inspection. If it is within the specified limits from batch record or Table 3, coordinate with Quality Assurance for Acceptable Quality Level (AQL). If it is NOT within the specified limits, inform supervisor and an investigation must be initiated as per IGN-001.

C. If first AQL testing fails, re-inspection of complete batch is performed with "100% Re-inspection" limits from Table 3. Once re-inspection is complete, a second AQL inspection can be performed with tightened inspection limits, as per IQA-016.

**NOTE: Only one re-inspection is allowed. If the reject rates are still NOT within the specified limits, an investigation must be initiated as per IGN-001.**

6.5.1.20 Once AQL inspection is complete and the batch record has been updated, the filled product can be further released for labeling and packaging.

A. If product is left unattended, ensure the product is secure (e.g., secured in a cage with fastener and lock).

6.5.1.21 If the filled product needs transfer to the warehouse, prepare the transfer by following the procedure in SOP IPK-003.

6.6 **Reduced Inspection Certification Program for Commercial Products:**

6.6.1 Manufacturing Science & Technology or Production Lead/designee are responsible for compiling results and report for the Reduced Inspection Certification Program.

6.6.2 Reduced Inspection Certification is performed based on the following criteria:

6.6.2.1 Execute First 100% and Second 100% Visual Inspections for three consecutive cGMP commercial manufacturing batches per container closure system or product and filling process line.

6.6.2.2 Once three consecutive cGMP visual inspection results are available, a summary report will be prepared evaluating if the process is well understood, visible particulates type and characteristics are determined, and the visual inspection process is in control to maintain reject rates.

6.6.2.3 The summary report will compare the consistency of results between the batches and ensure the results meet the following criteria.

A. Each defect category in each inspection meets the criteria in Table 3.

B. Defect types are consistent between the batches.

C. The reject rate from the Second 100% inspection is significantly lower than First 100% inspection (typically 50% less than First 100% inspection).

6.6.2.4 The summary report will be reviewed and approved by Quality Assurance Management through change control request.

6.6.2.5 Upon approval of change control, the respective Product Validated List (i.e., I-034) will be updated with reduced inspection for all future cGMP batches.

6.6.2.6 First 100% and Second 100% Visual Inspection should be performed for reduced inspection certified products if:

A. First 100% visual inspection reject rates are significantly higher and any new particle types are identified which originated from the process.

B. Primary container or closure manufacturer changes their process, which may affect particulates from packaging component.

C. Major changes are made in the aseptic fill process/equipment which may impact either particulate generation or particulate retention.

6.6.2.7 If the visual inspection results for certified products do not comply with above requirements, an investigation as per SOP IGN-001 is conducted and the product must be removed from the Reduced Inspection Program. The respective Product Validated List (i.e., EOL I-034) must be updated via change control to remove the product from the Reduced Inspection Program. The product will then be First and Second 100% inspected until the criteria is met once again as per the requirements of this SOP.

## 6.7 Inspection of Commercial Products Certified for Reduced Inspection Program:

6.7.1.1 All commercial products certified for Reduced Inspection Certification Program are one time 100% inspected (i.e., First 100% Inspection). To determine if the product is qualified for reduced inspection program, refer to the respective Product Validated List (i.e., EOL I-034).

A. Refer to Figure 3 for the general inspection process of commercial products certified for reduced inspection.

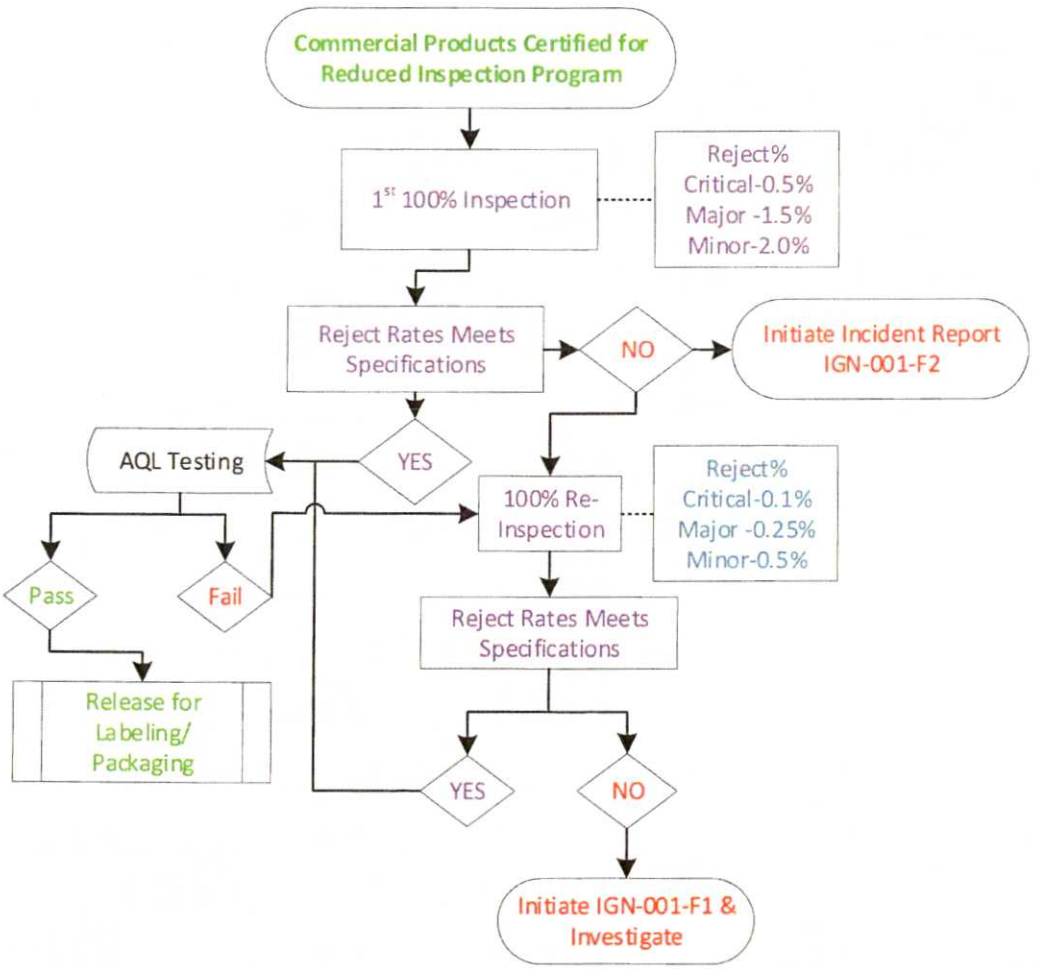



**Figure 3: General Visual Inspection of Commercial Products Certified for Reduced Inspection**

6.7.1.2 Before QA issues line clearance, ensure the product is secured (e.g., cage with fastener and lock, rack that has been wrapped) and there is no sign of tampering. If there is

evidence of tampering, notify supervisor or designee immediately to determine how to proceed.

6.7.1.3 Once line clearance has been given, bring product into the room and place a STATUS label on the rack/cage containing filled product (Status should be: To Be Inspected).

6.7.1.4 Place a STATUS label on the receiving rack/cage with appropriate status (e.g., First 100% inspected product)

6.7.1.5 Test light intensity using NIST calibrated standard Lux Meter prior to inspection start and record results in Form IPD-007-F1. Light intensity should be NLT 2100 lux approximately 8-10 inches from the light source. If the light intensity is less than 2100 lux the booth cannot be used for inspection, initiate a maintenance request as per SOP IGN-020.

6.7.1.6 Collect one Filled Units tub/tray to be inspected at a time from the batch of filled units. If filled units are in tubs count the number of units available for inspection and record number of units in the appropriate space on form IPD-007-F1 and check the First 100% inspection box. If filled units are in trays, prepare another empty tray to place inspected vials/syringes.

6.7.1.7 Pick up and hold the units in between finger and thumb in horizontal position (with bottom of the vial/syringe touching the thumb) approximately 8-10 inches below the light source and NMT 5 inches from the center line. Rotate and observe the containers, slowly, for five seconds in such a way that the complete body of the containers, including neck and bottom, is visible for inspection. Observe the containers for following defects:

A. For inspection of vials with Liquid Product:

a. Scratches/Scuff Marks on Body
b. Dents on Container
c. Dents on Flip-cap
d. Dirt on Exterior Surface
e. Empty Container
f. Cracked vial
g. Leakage
h. Missing Stopper
i. Missing Flip-cap
j. Incomplete seal/cap
k. Wrong color stopper/cap
l. Crimp defect (loose crimp or non-uniform crimp)

**NOTE: When inspecting for incomplete seal/cap, rotate unit between fingers and ensure the cap is leveled with the vial and the seal is securely locked from all points. Holding in one hand, move the cap head side to side and ensure the securing flanges do not move past the crown of the vial.**

B. For inspection of syringes with Liquid Product:

a. Scratches/Scuff Marks on Body
b. Dents on Container
c. Dents on needle sheath or luer lock
d. Dirt on Exterior Surface
e. Empty syringe
f. Cracked or broken syringes
g. Missing stopper

h. Wrong stopper position (stopper upside down) with reference to standard
i. Liquid between stopper ribs
j. Partially Inserted Stopper, with reference to standard

6.7.1.8 Gently swirl or invert the vials/syringes making sure that minimal air bubbles are introduced and bring back to an upright position. Inspect the product in front of the **black background** for minimum five seconds and check for the defects mentioned below, as applicable for vials or syringes with liquid product.

A. For inspection of Liquid Product in both vials and syringes:

a. Low Fill Level
b. High Fill Level
c. Discolored, or Cloudy/Precipitate
d. Colored particles
e. Black Particles
f. White Particles
g. Glass Particles
h. Fibers

6.7.1.9 Invert the vials/syringes momentarily and bring to an upright position and inspect the product in front of the **white background** for minimum five seconds and check for the defects mentioned below.

A. Black/Brown Particles
B. Fibers
C. Colored Particles

**NOTE: As each unit is inspected in front of black and white background each for a minimum of five seconds, and maximum of 2 containers are inspected at a time, it will take 20 seconds to inspect 2 units. No more than 360 units should be inspected per hour.**

6.7.1.10 Accepted vials/syringes will be placed into their respective tub/tray. Rejected vials/syringes will be marked with the defect code number as listed in IPD-007-F1 form section III and placed into the appropriate labeled reject bin (i.e., critical reject bin, major reject bin, minor reject bin).

**NOTE: If an inspector has a doubt about a defect category, another qualified inspector may inspect and confirm.**

6.7.1.11 At the end of inspection process, test light intensity using NIST calibrated standard Lux Meter, and record in Form IPD-007-F1. Light intensity should be NLT 2100 lux approximately 8-10 inches from the light source; if the light intensity does not meet specification, initiate a maintenance request as per SOP IGN-020. All units inspected in this booth must be re-inspected after taking corrective action/repair or perform inspection in any other inspection booth.

6.7.1.12 Individual operators will reconcile the inspected units and rejects in his/her form and attach to the batch record.

6.7.1.13 Review total reject rates from the first 100% inspection through respective inspection forms. If the reject rate acceptance criteria are not specified in the Batch Manufacturing

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Record, follow the limits specified in Table 4. If it is within the specified limits, coordinate with Quality Assurance for Acceptable Quality Level (AQL) Inspection.

Table 4: Reduced Inspection Certified Products Visual Inspection Acceptance Criteria

| Type of Defects | % Reject Rates (Action Level) | |
|---|---|---|
| | First 100% Inspection | 100% Re-inspection |
| Critical Defects | 0.5 | 0.1 |
| Major Defects | 1.5 | 0.25 |
| Minor Defects | 2.0 | 0.5 |

**NOTE: If First 100% Inspection reject rates are within the specified limits, then a comment should be made in the Batch Manufacturing Record for Second 100% Inspection results referring to the Reduced Inspection Certification.**

A. If the reject rates from the first 100% inspection are NOT within the specified limits, initiate an incident report as per SOP IGN-001 and request Quality Assurance Document Control to issue respective Batch record pages and Form IPD-007-F1 for 100% Re-inspection as per SOP IQA-006.

B. Review total reject rates from 100% re-inspection. If it is within the specified limits from batch record or Table 4 "**100% Re-inspection**", coordinate with Quality Assurance for Acceptable Quality Level (AQL).

C. If first AQL testing fails, re-inspection of complete batch is performed with "100% Re-inspection" limits from Table 4 after initiating an incident report as per SOP IGN-001. Once re-inspection is complete, a second AQL inspection can be performed with tightened inspection limits, as per SOP IQA-016. If it is NOT within the specified limits, inform supervisor. An investigation must be initiated as per IGN-001.

**NOTE: Whenever the "100% re-inspection" and final AQL pass the requirements, the decision of removing the commercial product from the reduced inspection program is assessed and discussed in the respective incident / investigation report based on the nature of the defect.**

6.7.1.14 Once AQL inspection is complete and the batch record has been updated, the filled product can be further released for labeling and packaging.

A. If product is left unattended, ensure the product is secure (e.g., secured in a cage with fastener and lock).

6.7.1.15 If the filled product needs transfer to the warehouse, prepare the transfer by following the procedure in SOP IPK-003.

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6.8 Handling of Difficult to Inspect Products:

6.8.1 Some products may be difficult to inspect for particulates (e.g., colored products for Research and Development & Commercial). If a product cannot be reliably inspected following the procedures above, the following method will be used for inspection.

6.8.1.1 The product will undergo first 100% inspection, AQL inspection, and destructive testing. Refer to Figure 4 for the general inspection process for difficult to inspect products.

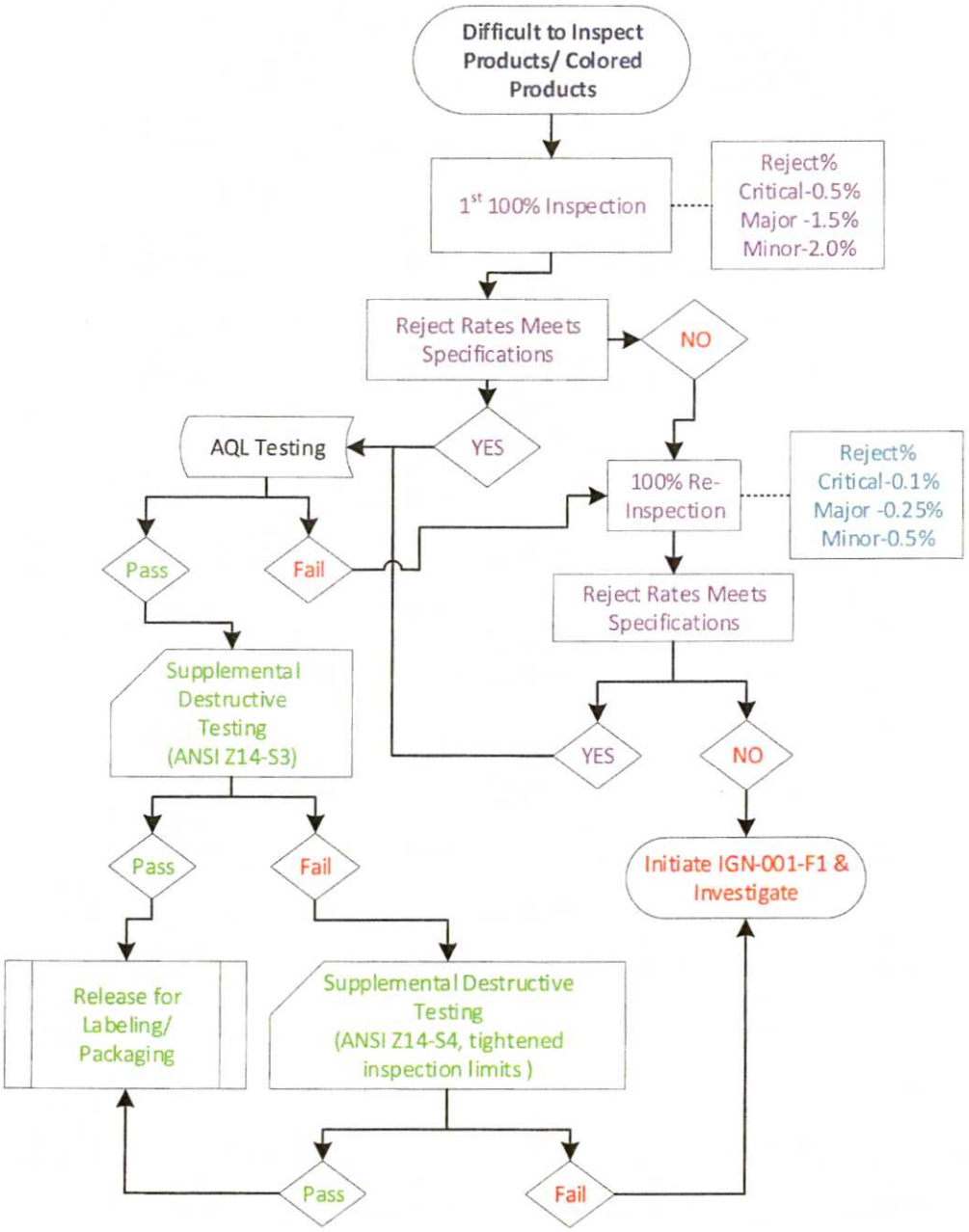



**Figure 4: General Visual Inspection Process for Difficult to Inspect Products**

6.8.1.2 Review total reject rates from the first 100% inspection through respective inspection forms. If the reject rate acceptance criteria are not specified in the Batch Manufacturing Record, follow the limits specified in Table 5. If it is within the specified limits, coordinate with Quality Assurance for Acceptable Quality Level (AQL) Inspection.

Table 5: Difficult to Inspect Products Visual Inspection Acceptance Criteria

| Type of Defects | % Reject Rates (Action Level) | |
|---|---|---|
| | First 100% Inspection | 100% Re-inspection |
| Critical Defects | 0.5 | 0.1 |
| Major Defects | 1.5 | 0.25 |
| Minor Defects | 2.0 | 0.5 |

A. If the reject rates from the first 100% inspection are NOT within the specified limits, request Quality Assurance Document Control to issue respective Batch record pages and Form IPD-007-F1 for 100% re-inspection as per SOP IQA-006.

B. Review total reject rates from 100% re-inspection. If it is within the specified limits from batch record or Table 5 "**100% Re-inspection**", coordinate with Quality Assurance for Acceptable Quality Level (AQL).

C. If first AQL testing fails, re-inspection of complete batch is performed with "100% Re-inspection" limits from Table 5. Once re-inspection is complete, a second AQL inspection can be performed with tightened inspection limits, as per SOP IQA-016. If it is NOT within the specified limits, inform supervisor. An investigation must be initiated as per IGN-001.

6.8.1.3 Once production and AQL inspections are complete, QA department will take samples following Form IQA-016-F2 American National Standard (ANSI Z1.4) Sampling Plan, Special Inspection level S3 for supplemental destructive testing, by either an in-house or outside laboratory.

6.8.1.4 Transfer the samples to in-house laboratory for testing or to Warehouse to prepare samples for shipping.

A. In-house testing is performed as per SOP IMI-038 "Determination of Particulate within Injectables Products using Filtration Method".

B. If supplemental destructive testing does not meet the acceptance criteria, retesting is performed with tightened parameters.

At this time, QA department will take additional samples following Form IQA-016-F2 American National Standard (ANSI Z1.4) Sampling Plan, Special Inspection level S4 with tightened inspection limits for retesting of supplemental destructive testing.

If retesting does not meet the acceptance criteria, an investigation is initiated as per SOP IGN-001.

6.8.1.5 Once AQL inspection and supplemental testing are complete and the batch record has been updated, the filled product can be further released for labeling and packaging.

A. If product is left unattended, ensure the product is secure (e.g., secured in a cage with fastener and lock).

6.8.1.6 If the filled product needs transfer to the warehouse, prepare the transfer by following the procedure in SOP IPK-003.

6.9 Reconciliation of Visually Inspected Product:

6.9.1 After complete inspection, Production Supervisor or designee will review each IPD-007-F1 with IPD-007-F3 to ensure each tub/tray was inspected as per established inspection program and all units are accounted for.

6.9.2 Production Supervisor or designee will check each tub/tray's inspections and acknowledge in respective space in Form IPD-007-F3.

6.9.3 Production Supervisor or designee will then check the number of units available for each inspection, number of units rejected in each inspection, and number of units available after complete inspection.

6.9.4 Form IPD-007-F3 and Batch Manufacturing Record inspection results must be reviewed and found acceptable by Production Supervisor or designee prior to labeling or packaging of visually inspected product.

6.10 Handling of Rejected Units:

6.10.1 Once Visual Inspection is finished and the appropriate forms and Batch Record pages are complete, the rejected units will be placed into a storage container (e.g., box, resealable bags). Production will complete the label shown in Figure 5 and place it on the storage container.

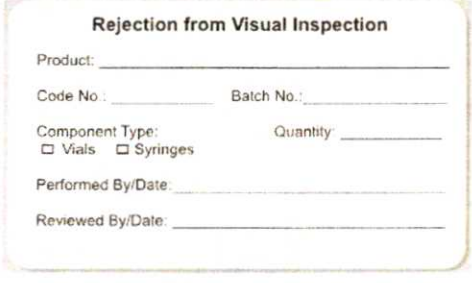



**Figure 5: Rejection from Visual Inspection Label Template**

6.10.2 Production will take labeled storage container to warehouse. Warehouse and production will place the storage container into the "REJECT" cage and production will document in the appropriate logbook.

6.10.3 Once the batch has been released by QA and no further testing is needed, QA will notify production and warehouse personnel.

6.10.4 Production designee will complete form IGN-024-F1 for the rejected units and give the completed form to warehouse.

6.10.5 Warehouse personnel will follow the waste procedure outlined in IWH-004 to dispose of the rejected units.

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6.10.6 If the inspection is outside the specified acceptance criteria, production supervisors may determine that testing and identification of particulates is needed for a product. If so, production will send samples from the respective batch to either an in-house or outside laboratory using the following procedure.

6.10.6.1 Take the rejected units from warehouse to appropriate inspection room.

6.10.6.2 Separate the units into groups of similar particulate types (e.g., colored fiber, white fiber, dark fiber).

6.10.6.3 Choose a representative sample from each particulate type to send for testing.

6.10.6.4 Transfer the representative sample to QC laboratory for testing or to Warehouse to prepare samples for shipping. Return remaining rejected units to the warehouse.

6.11 Trending of Visual Inspection Results:

6.11.1 Visual inspection results for each cGMP batch will be tabulated and trended on a quarterly basis (once every three months) to ensure that manufacturing and inspection processes are operating in control.

6.11.2 Trending is performed to compile results and identify possible anomalies such as abnormal defect type or number of defects observed in a single product or container/closure system.

6.11.3 A report of the trend will be written and reviewed accordingly.

6.11.4 Visual inspection results for products certified for reduced inspection program are reviewed to ensure the product still qualifies for reduced inspections. In case a product no longer qualifies for the reduced inspection program, the product must be removed through change control procedure and revision of respective Product Validated List (i.e., EOL I-034).

6.11.5 Based on the results obtained, Corrective and Preventive Action (CAPA) may be proposed as per SOP IQA-024 if required.

## 7.0 REVISION HISTORY

| Revision No. | Effective Date | Description of Changes |
|---|---|---|
| 01 | FEB 05 2019 | Original SOP |
| 02 | JUL 29 2019 | 1. Added IWH-004, IQA-006, IPK-003, IGN-024, and IGN-024-F1 to reference section.<br>2. Add Second 100% inspection in Figure 1.<br>3. Clarified section 6.1.7 for taking and documenting breaks<br>4. Clarified section 6.1.8 for use of the magnifier.<br>5. Clarified section 6.2.2.2 for verifying cleanliness on the Visual Inspection Booth.<br>6. Changed section 6.2.4.2 to initiate a maintenance request as an incident is not needed.<br>7. Updated section 6.3 title to Procedure for Manual Visual Inspection and modified and realigned section for a Second 100% Inspection.<br>8. Removed duplicate defects in section 6.3.5.1.J and 6.3.5.1.K.<br>9. Added note after section 6.3.3.3.A for inspecting incomplete seal/cap<br>10. Modified Section 6.3.6.1 to include syringes and removed section 6.3.6.2.<br>11. Added 6.4 Handling of Rejected Units. |
| 03 | DEC 11 2019 | 1. Added note after section 6.3.4.1 for use of tray partitions when packing units into trays.<br>2. Added section 6.4 for handling of difficult to inspect products.<br>3. Added section 6.5.6 for testing and identification of particulates procedure. |

| SOP No. | Title | Revision No. |
|---|---|---|
| IPD-007 | VISUAL INSPECTION OF INJECTIONS | 09 |

| Revision No. | Effective Date | Description of Changes |
|---|---|---|
| 04 | OCT 15 2020 | 1. Included Note between steps 6.3.2 and 6.3.3 to explain procedure for sample collection when they must be taken prior to completion of visual inspection. |
| 05 | DEC 02 2020 | 1. Included Note between steps 6.3.3.8 and 6.3.3.9 to establish a limit on the number of units inspected per hour. |
| 06 | MAR 16 2020 | 1. Updated Section 3.0 for Trending Responsibilities.<br>2. Moved procedure for placing inspected units into Tray to Section 6.3.4.10.<br>3. Added Section 6.6 for Trending of Visual Inspection Results. |
| 07 | FEB 07 2022 | 1. Changed wording from "tub" to "container" in case of inspection of units in tubs, trays, etc.<br>2. Note was added in Section 6.4 for taking samples of difficult to inspect products.<br>3. Added Section 6.3.5 for Reconciliation of Visually Inspected Product. |
| 08 | MAY 19 2022 | 1. Entire SOP is re-arranged to accommodate visual inspection based on product stage of life cycle.<br>2. Change in % Reject Rates based on industry standards and guidance.<br>3. Introduced "Reduced Inspection Certification Program".<br>4. Other minor changes to maintain the flow of inspection requirements depending on batch type. |
| 09 | OCT 20 2022 | 1. Change syringe defect description from "Distance between stopper and top liquid level" to "Partially Inserted Stopper", in respective sections |

| SOP No. | Title | Revision No. |
|---|---|---|
| IGN-025 | ASEPTIC PROCESS SIMULATION (APS) OR MEDIA FILL PROGRAM | 04 |

| Prepared By / Date | Reviewed By / Date | QA Approved By / Date | Effective Date |
|---|---|---|---|
| 04/07/23 | PMK 04/07/23 | M. Salazar 04/10/23 | APR 2 6 2023 |
| Title: Asst. Manager | Title: Manager-MS | Title: CQCO | Change Control No. I-23296 |

## 1.0 PURPOSE

The purpose of this SOP is to establish and implement the Aseptic Process Simulation (APS), also called Media Fill Validation to support sterile drug products manufacturing.

The purpose of an Aseptic Process Simulation (APS) is to:

1.1 Assess the capability of an aseptic process under a given manufacturing environment and process controls.

1.2 Demonstrate that appropriately designed and implemented process changes are acceptable.

1.3 Demonstrate compliance with current Good Manufacturing Practices.

1.4 Demonstrate the appropriateness of operating practices used in support of aseptic processing.

1.5 Challenge the aseptic process for microbial contamination vulnerabilities.

## 2.0 SCOPE

The procedure is applicable for Sterile Drug Products Manufacturing facility at BPI Labs.

## 3.0 RESPONSIBILITY

3.1 Manufacturing Science & Technology (MS) / Production (PD):

3.1.1 Prepare, review, and execute the media fill Batch Record, Protocol, and the Final Report.

3.1.2 Provide the environmental summary report for non-viable particulate air, relative humidity, temperature, and differential pressure monitoring conducted during the media fill.

3.2 Microbiology:

3.2.1 Incubate and inspect incubated media filled units and remaining bulk media at the completion of incubation.

3.2.2 Provide the summary report for the examination of the media filled units to MS for inclusion with the media fill report.

3.2.3 Provide the environmental summary report for viable air and surface monitoring conducted during the media fill.

3.3 Quality Assurance:

3.3.1 Review and approve the media fill batch record and final media fill report.

3.3.2 Maintain the media fill schedule (every 6 months per filling line and process) to maintain bracketing and ensure the qualified status of the aseptic processing is maintained.

## 4.0 REFERENCES

4.1 CFR Title 21 Part 211.113 Control of microbiological contamination

4.2 USP General Chapters: <1116> MICROBIOLOGICAL CONTROL AND MONITORING OF ASEPTIC PROCESSING ENVIRONMENTS

4.3 USP General Chapters: <1208> STERILITY TESTING-VALIDATION OF ISOLATOR SYSTEMS

4.4 USP General Chapters: <1211> STERILITY ASSURANCE

4.5 Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice FDA, September 2004

4.6 PDA Technical Report No. 22 (Revised 2011), Process Simulation for Aseptically Filled Products

4.7 Food and Drug Administration Compliance Program Guidance Manual Chapter 56 – Drug Quality Assurance - Subject-Sterile Drug Process Inspections

4.8 SOP IGN-001 Investigations

4.9 SOP IQA-024 Corrective and Preventive Actions

4.10 SOP IWH-004 Storage and Disposal of Manufacturing and Laboratory Waste

4.11 VMP-I01 Validation Master Plan for BPI Labs

4.12 IPD-RA-1-IPD-FM01-01 Risk Assessment Aseptic Process Simulations (Media Fills) for Robotic Aseptic Fill Machine (ID. 1-PD-FM01-01)

4.13 IPD-RA-1-IPD-FM02-01 Risk Assessment Aseptic Process Simulations (Media Fills) for FlexPro Robotic Aseptic Fill Machine (ID. 1-PD-FM02-01)

## 5.0 ATTACHMENTS

Not Applicable.

## 6.0 PROCEDURE

6.1 General:

6.1.1 BPI Labs aseptic fill process is designed to perform within a Grade ISO 5 environment, through use of robotic isolators, both gloved and gloveless.

6.1.2 Gloveless isolators eliminate human interventions and human originated microbial contamination risk is eliminated from aseptic fill in Sterile Drug Products fill finish. Due to this reason, some traditional elements of aseptic process are not applicable, such as, but not limited to, personnel gowning qualification and personnel monitoring during fill.

6.1.3 Gloved Isolators are designed to fill with no direct human interaction. Isolator designed with gloves ports are used in the event of necessary adjustments to the fill machine within ISO 5 environment.

6.1.4 Sterile Drug Products Manufacturing is designed either by means of aseptic filling or aseptic filling followed with terminal sterilization of product in its final container/closure system.

6.1.5 APS is only required for all products manufactured using aseptic process. If terminal sterilization is used, no media fill support is required since these products are subjected to subsequent terminal sterilization. This provides the necessary Sterility Assurance Level (SAL) for those products, provided sufficient pre-sterilization hold time studies have been established.

6.1.6 Processes to be challenged in process simulation:

The conduct of process simulations for aseptically produced parenteral products entails simulation of the process from the point of sterilization of the product and product contact surfaces, including containers and closures, through sealing of the filled container. Process such as weigh dispensing, mixing, pre-sterilization/filtration, and post sealing does not require to be simulated, similarly to the product process.

6.1.6.1 Compounding/Mixing and Sterile Filtration Operation: After sterilization, the medium should be passed through the equipment train. as though it were an actual production batch, and all routine aseptic procedures used in the manufacture of a batch should be performed, e.g., sampling, aseptic connection. Any aseptic manipulations performed during and at the end of the holding period should be simulated as well.

6.1.6.2 Filling Operation: The containers and closures (if necessary), product contact equipment, and filling parts should be prepared using standard operating procedures (SOPs). The filling machine should be operated at the pre-determined conditions for the container size being utilized based on risk assessment and "worst case" conditions.

A. For a process conducted in an isolator or robotic aseptic operations, where there is a low risk of contamination because of the lack of direct human intervention, a standard quantity of NLT 3,500 containers is sufficient to perform operations and interventions. For container formats with larger sizes and less containers per nest (formats greater than 10mL filling volume), a standard of NLT 1,200 containers is sufficient. This would yield a similar or greater number of nests required to complete the batch, similarly allowing for all required operations and interventions to be performed.

B. For traditional aseptic fills under Laminal Air Flow hoods, with manual aseptic operations and interventions:

a. When the production batch size is above 10,000 units, a minimum of 10,000 units is sufficient to perform all operation and interventions.
b. When the production size is below 5,000 units, at least equal the maximum batch size.

6.2 APS Strategy:

6.2.1 Media fill runs and required frequencies are listed in Table 1.

Table 1: Media Fill Strategy

| When to Perform | How Many | Action | Reporting System |
|---|---|---|---|
| When a processing line is being initially qualified, including new facility construction and new filling line installation. | At least three separate, consecutive, successful runs | Any one size container | Protocol & Report |
| When introducing new container/closure size outside of the established bracket. | At least three separate, consecutive, successful runs | Specific container/closure | Protocol & Report |
| When introducing new container/closure type (e.g. syringes). | At least three separate, consecutive, successful runs | Specific container/closure | Protocol & Report |
| Once initially qualified, every six (6) months ± 1 month (semi-annually). | One successful run | Alternating with each end of the bracket (e.g., largest, smallest) | Protocol & Report |
| Facility and equipment modifications, such as breach to the sterile/aseptic area/isolator and line configuration changes. | Revalidation as per Change Control assessment | Impact assessed via Change Control | Protocol & Report |
| When using alternate filtration or filling assembly, such as Multi-Use flow path instead of Single-Use flow path. | One successful run | Impact assessed via Change Control | Protocol & Report |
| Minor modifications in Flow paths or sterile filtration/filling assembly, such as alternate use of sterile connector or change in product holding container size, material, etc. | One successful run | Impact assessed via Change Control | Protocol & Report |
| Anomalies in environmental testing results from filling operation, container closure system changes, extended shutdowns, or sterility testing failure due to fill system failures. | Impact assessed via Change Control | Impact assessed via Change Control | Impact assessed via Change Control |

6.2.2 A detailed APS strategy and guidance written in the Validation Master Plan of BPI Labs should be followed to perform media fills.

6.3 Risk Assessment (RA):

6.3.1 Risk Assessment is performed per fill line to determine container closure configurations, identify, and evaluate the aseptic process steps, interventions, and worst-case conditions that can potentially adversely affect the sterility assurance risk to the product and incorporate in the APS.

6.4 Media Fill Matrix:

6.4.1 A matrix will be prepared based on the Risk Assessment to include validated Media Fills.

6.4.2 Specific conditions that represent the worst case(s) will be identified within the matrix. The matrix and specific criteria for assessment and inclusion of Media Fills must be documented and approved by Quality Assurance or designee.

6.5 Execution of Media Fill Validation:

6.5.1 Batch Record preparation and execution:

6.5.1.1 It should be written in the same format as a normal production batch record and contain all the routine data and sign-off requirements. All information applicable to the process simulation, which normally would be attached to a batch record, also should be attached to the simulation batch record, e.g., cleaning and sterilization records for pieces of equipment used, release stickers for the containers and closures, etc. All interventions, whether inherent (integral component of the process) or corrective (required to maintain operation), and stoppages, should be documented in the batch record as the type of intervention, time the intervention occurred, aseptic operators involved with the duration of the intervention or stoppage, and the number of the tub or tray being filled. The executed batch record should include information which is relevant to the performance and completion of the study. This includes but is not limited to:

A. Names of individuals participating in the simulation

B. Media sterilization/filtration

C. Filter identification and membrane integrity test results

D. Record or log of routine and non-routine occurrences including those in the filling room, which may have an effect on the outcome of the study

E. Number of units filled

F. Number of units rejected for cause during pre-incubation inspection (e.g. damaged container, defective seal)

G. Number of units incubated

H. Filled unit incubation time, temperature, and duration

I. Number of units positive and tub or tray number of any positive unit(s)

J. Growth promotion of medium (after incubation)

K. Filled unit accountability

L. Environmental and personnel monitoring (if applicable) results

M. The description and resolution of any discrepancies or deviations to the protocol

N. The executed batch record should be approved, signed, and dated

6.5.2 Validation Protocol and Report Preparation:

6.5.2.1 A formal written protocol or procedure should be prepared, approved, and issued prior to the start of the study. The document should include but not limited to the following information:

A. Groups responsible for execution, microbial testing, and approval of study

B. Rationale for the "worst case" parameters chosen as appropriate simulation of routine operations

C. Identification of the process to be simulated

D. Identification of the room or rooms to be used

E. Identification of the filling line and equipment to be used, including fluid path configuration details if multiple configurations are available

F. Type of container/closure to be used

G. Line speed

H. Minimum number of units to be filled

I. Number and type of interventions and stoppages

J. Identification of units to be excluded from incubation and rationale

K. Media to be used

L. Volume of medium to be filled into the containers

M. Incubation time, temperature, and duration for the filled units

N. Environmental monitoring to be performed

O. Accountability requirements

P. Acceptance criteria for all activities

Q. Description of the documentation required for the final report

R. Duration of the aseptic process simulation

S. Duration of routine production fills being simulated

T. Definition of conditions that may cause the simulations to be invalidated and decision-making authority

6.5.3 Pre-Incubation Container Inspection:

6.5.3.1 Prior to incubation 100% media filled units are visually inspected for non-integral units (e.g., missing, or misaligned closures, cracks in container) due to the possible breach of product sterility, according to the Master Batch Manufacturing Record instructions.

6.5.4 Incubation:

6.5.4.1 All pre-inspected media filled units must be incubated for at least 7 days at 22.5°C ± 2.5°C (where vials will be inverted), followed with another at least 7 days at 32.5°C ± 2.5°C (where vials will be upright), in temperature-controlled incubators. Syringes are always incubated upright as product is always in contact with the stopper.

6.5.5 Post-Incubation Container Inspection:

6.5.5.1 At the end of each incubation condition, visual inspection of all units for growth is performed by microbiologist or qualified operator.

6.5.6 Acceptance Criteria:

6.5.6.1 When filling fewer than 5000 units, no contaminated units should be detected.
A. One (1) contaminated unit is considered cause for revalidation, following an investigation.

6.5.6.2 When filling from 5,000 to 10,000 units:

A. One (1) contaminated unit should result in an investigation, including consideration of a repeat media fill.

B. Two (2) contaminated units are considered cause for revalidation, following investigation.

6.5.6.3 When filling more than 10,000 units:

A. One (1) contaminated unit should result in an investigation.

B. Two (2) contaminated units are considered cause for revalidation, following investigation.

6.5.6.4 Leftover Media in the container/bags:

A. Samples are taken from the leftover media in the container/bags and are submitted for incubation. The samples from the leftover media are representative of the container they were attached to, but are not directly representative of the final units being filled as part of the media fill.

6.5.6.5 Investigations should be performed per SOP IGN-001.

6.6 Initial APS:

6.6.1 Initial APS is performed in the events discussed in Table 1.

6.6.2 Upon completion of facility, utility, and equipment qualification, risk assessment is prepared by MS and approved to all departments involved, along with Quality Assurance.

6.6.3 Three (3) consecutive, separate, successful, runs are executed and included in an Effective Official List.

6.6.4 Quality Assurance controls the schedule to re-qualify each media fill based on a six-month period. Schedule is circulated to the concerned departments every month to ensure media fill program to the specific container closure systems are in valid state.

6.7 Continued Process Simulation Verification:

6.7.1 The bracketing approach will be maintained as the basis for requalification. APS is to be performed every six months for each processing line / fill machine, alternating between smallest and largest, as well as alternating container/closure systems, to maintain qualification of the aseptic filling operations.

Example:

Process Simulations for Vanrx Formats are bracketed by 2R vials and 50R vials, as well as 1mL syringes and 10mL syringes. As such, process simulations can be performed in the following order: 2R Vials -> 10mL Syringe -> 1mL Syringe - > 50R Vials. This would repeat back to 2R Vials and the order repeats.

6.7.2 An Initial Protocol will be created for initial qualification. A verification Protocol will be created and reissued for requalification, when applicable. These protocols will be used for execution of media fill runs for the specific run.

6.7.3 Quality Assurance updates media fill history and schedule to ensure that the process bracketing is maintained.

6.8 Disposal of Media Filled Containers and leftover media:

6.8.1 After completion of the incubation, media filled containers are disposed of per SOP IWH-004, unless there is a pending investigation related to the media fill or GPT failure of the media used.

6.9 Media Fill Failure Investigation:

6.9.1 Any contaminated unit cause for an investigation (as per IGN-001) should include a comparison, and analysis, of environmental monitoring performed during the media fill. If an assignable cause is identified, a single re-validation run will be planned. If no root cause is found for a process simulation failure, three consecutive, successful process simulations are required for re-qualification.

6.9.2 The investigation into a failed APS will include the following activities:

6.9.2.1 Identification of microorganisms, preferably to species level, to aid in the determination of the possible sources of the contamination.

6.9.2.2 Review of the data of microbial environmental monitoring and airborne particulate monitoring.

6.9.2.3 Review of the sterilization / depyrogenation cycles of container / closures, components, equipment, and filter integrity test data of filters used for filtration.

6.9.2.4 Review qualification documents of the HEPA Filters (integrity when challenged with aerosol, airflow direction, velocity measurements, air flow patterns, and pressure differentials).

6.9.2.5 Review of interventions and batch report from filler for any unusual events that occurred during the media fill.

6.9.2.6 Review of the procedure adopted during the intervention.

6.9.2.7 Storage condition of sterile items, disinfection procedures, and training.

6.9.2.8 Review of the equipment qualification, such as autoclave sterilization performance qualifications.

6.9.2.9 Post filter integrity test data of the filters used in the media fill.

6.9.2.10 Evidence of power failure and all deviations that occurred during the process.

6.9.2.11 Evaluation of incubated bulk media.

6.9.2.12 The investigation must be directed towards identification of the root cause of the failure and suggest the corrective and preventive actions to be taken in order to prevent failure. Refer to SOP IQA-024.

6.9.2.13 Based on investigation performed by manufacturing, QA will perform a risk assessment and assess the impact on all product filled on the affected fill line since the last acceptable APS, and determine the disposition of released product, as well as the product in-process.

6.9.2.14 After incubation is underway, any unit found to be damaged should be included in the data for the media fill run, because the units can be representative of drug product released to the market. Any decision to exclude such incubated units (i.e., non-integral) from the final run must be fully justified through a deviation. If a correlation emerges between difficult to detect damage and microbial contamination, a thorough investigation should be conducted to determine its cause.

6.10 Invalidation of APS or abortion of media fill will occur in the following conditions:

6.10.1 When growth promotion test (GPT) of media fails.

6.10.2 When filtered media shows mass growth in bulk solution.

6.10.3 Under circumstances in which written procedures require commercial lots to be equally handled, such as:

6.10.3.1 Filter integrity test failure which would have resulted in product re-filtration or rejection.

6.10.3.2 Failure of physical conditions in the isolator (e.g., power outage).

6.10.3.3 Any major breakdown in the fill equipment, which requires to open the isolator.

6.10.4 If for any reason the media fill run is considered invalid/aborted, containers should not be incubated.

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| IGN-025 | ASEPTIC PROCESS SIMULATION (APS) OR MEDIA FILL PROGRAM | 04 |

6.10.5 All media filled units filled before an incident that would cause an aborted fill must be incubated.

6.10.6 Invalidation of APS or abortion of media fill will be documented through the respective section in the appropriate protocol. Investigation should be performed per SOP IGN-001.

6.11 New Product or Container Closure Introduction:

6.11.1 Change control will be initiated for new product and container closure introduction. The team, including Quality Assurance, will evaluate the need for a media fill.

6.11.2 If the product being evaluated falls in the already validated container closure configuration, no additional media fills are required, e.g. Product "A" container closure system is 2R vial, 13mm neck with 13mm stopper cap as closure, and the new product "B" introduced is also is 2R vial, 13mm neck with 13mm stopper cap as closure.

6.11.3 If the new container closure is out of the bracketing range established, media fill must be performed for at least three consecutive separate successful runs for that container closure. For example, if bracketing is for 2R vial with 13mm neck and 13mm stopper cap, and 10R vial with 20mm neck and 20mm stopper cap, the 4R, 6R, and 8R vials with 20mm neck and 20mm stopper cap do not require media fill, however the 100R vial with 32mm neck with 32mm stopper cap does require 3 consecutive successful media fills.

6.11.4 New product manufacturing process is evaluated for aseptic operations and any additional interventions or process conditions, other than the previously validated, must be reviewed for criticality.

## 7.0 REVISION HISTORY

| Revision No. | Effective Date | Description of Changes |
|---|---|---|
| 01 | DEC 07 2018 | Original SOP |
| 02 | FEB 04 2011 | 1. Include Risk Assessment in references section.<br>2. Include different scenarios in Table 1.<br>3. Expand on continued process simulation verification in step 6.7.1. Procedure and example included for alternating container closure system. |
| 03 | JAN 31 2023 | 1. Include Risk Assessment for new fill machine (FM02) in references section<br>2. Split up section 6.1.1 to elaborate the use of both gloved and gloveless isolators<br>3. Include sections under new 6.1.6.2 detailing the required amount of containers to be challenged during process simulation. |
| 04 | APR 2 6 2023 | 1. Modified Step 6.1.6.2.A to specify that 1,200 containers is sufficient for container/closure formats with a fill volume greater than 10mL<br>2. Step 6.5.6.4.A reworded to specify that leftover media is incubated from samples taken from the containers.<br>3. Clarified wording for example in Step 6.7.1 |

| SOP No. | Title | Revision No. |
|---|---|---|
| IGN-033 | HANDLING OF 503B PRODUCTS | 08 |

| Prepared By / Date | Reviewed By / Date | QA Approved By / Date | Effective Date |
|---|---|---|---|
| Kirtan. R. Patel 08/30/21 | 08/31/21 | M. Salazar 08/31/21 | AUG 3 1 2021 |
| | | | Change Control No. |
| Title: QA Specialist | Title: Pharmacist | Title: CQCO | I-21419 |

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## 1.0 PURPOSE

The purpose of this SOP is to establish general guidelines for the handling of 503B Injectable Sterile Drug Products at BPI Labs facility Suite 450.

## 2.0 SCOPE

This procedure is applicable to 503B Injectable Sterile Drug Products manufactured at BPI Labs facility Suite 450.

For Solid Dosage Products manufactured at Suite 420A, refer SOP GN-040 Handling of 503B Products (Solid Dosage).

## 3.0 RESPONSIBILITY

3.1 It is the responsibility of every department listed in this procedure to follow instructions delineated in each section.

3.2 It is the responsibility of Operations and Quality Assurance Management to ensure that all activities included in this procedure are followed in the development of 503B drug products.

## 4.0 REFERENCES

4.1 Guidance for Industry Sterile Drug Products Produced by Aseptic Processing Current Good Manufacturing Practice Sept 2004

4.2 Contract Manufacturing Arrangements for Drugs: Quality Agreements

4.3 Bulk Drug Substances Used in Compounding Under Section 503B of the FD&C Act

4.4 Current Good Manufacturing Practice – Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act

4.5 Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act

4.6 Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

4.7 Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food Drug and Cosmetic Act

4.8 21 CFR Part 310 – New Drugs, Subpart D – Records and Reports, Section 310.305

4.9 Florida Department of Health Board of Pharmacy Rule 64B16-28.100 Pharmacy Permits – Applications and Permitting

4.10 ICH Guidance for Industry Q1A(R2) Stability Testing of New Drug Substances and Products

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4.11 Protocol IFC-PQ-T-1-AH-02,1-AH-03,1-AH-04 HVAC System (ID No. 1-AH-02, 1-AH-03, 1-AH-04) Performance Qualification Protocol

4.12 SOP GN-040 Handling of 503B Products (Solid Dosage)

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4.13 SOP ICB-001 Calibration Procedure

4.14 SOP IGN-001 Investigations

4.15 SOP IGN-003 Creation and Modification of Code Numbers and National Drug Code Numbers (NDC)

4.16 SOP IGN-006 Development of Products

4.17 SOP IGN-010 Personnel Gowning, Sanitation, Health Habits, Health Conditions

4.18 SOP IGN-017 Personnel Flow in BPI Labs Suite 450

4.19 SOP IGN-018 Material Flow in BPI Labs Suite 450

4.20 SOP IGN-019 Handling of Purified Water, Water for Injection, Pure Steam, and City Water

4.21 SOP IGN-023 Preparation of Master Batch and Packaging Records

4.22 SOP IGN-025 Aseptic Process Simulation (APS) or Media Fill Program

4.23 SOP IGN-027 Preparation of Cleaning Agents, Detergents, and Disinfectants Used in Manufacturing

4.24 SOP IGN-028 Cleaning of Processing and Non-Processing Rooms

4.25 SOP IGN-030 Operation of the Building Management System

4.26 SOP IGN-036 Serialization Procedure

4.27 SOP IMI-003 Out of Specification Microbiology Results

4.28 SOP IMI-005 Preparation, Maintenance, and Growth Promotion of Culture Media

4.29 SOP IMI-006 Growth Promotion Test

4.30 SOP IMI-020 Environmental Monitoring Program (Viable) for Sterile Drug Manufacturing Area

4.31 SOP IMI-034 Handling of Microbiology Laboratory Incidents

4.32 SOP IPC-001 Purchasing System

4.33 SOP IPD-002 Dispensing of Raw Material and Packaging Material

4.34 SOP IPD-006 Time Limitations for Production and Cleaning

4.35 SOP IPD-007 Visual Inspection of Injections

4.36 SOP IPD-FM01-1 Set Up and Operation of the Robotic Aseptic Fill Machine (Model # SA25)

4.37 SOP IPD-SS01-1 Set Up and Operation of the Steam Sterilizer (Model # FOAF3/AG)

4.38 SOP IPK-001 Labeling and Packaging Operation

4.39 SOP IPK-002 Issuance, Reconciliation, Destruction, and Return of Printed Labeling Material

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4.40 SOP IPK-003 Brite Stock Handling

4.41 SOP IPH-001 503B - Research and Development Experimental Trial Batches

4.42 SOP IPH-002 BPI Policy for Essentially Copies of Approved Drug Products

4.43 SOP IQA-001 Change Control System

4.44 SOP IQA-002 Document Control System

4.45 SOP IQA-003 Identification and Numbering System

4.46 SOP IQA-005 Monitoring of Environmental Conditions

4.47 SOP IQA-006 Issuance of Batch Records, Packaging Records, Protocols, and In-House Computer-Generated Labels

4.48 SOP IQA-007 Sampling System

4.49 SOP IQA-009 Handling of Complaints

4.50 SOP IQA-010 Vendor Qualification Program

4.51 SOP IQA-011 Disposition Procedure

4.52 SOP IQA-012 Retesting of Materials and Products

4.53 SOP IQA-013 Quality Control Unit and Management

4.54 SOP IQA-020 Retention Samples

4.55 SOP IQA-021 Procedure for Reviewing Executed cGMP Documents

4.56 SOP IQA-024 Corrective and Preventive Actions

4.57 SOP IQA-025 Statistical Techniques

4.58 SOP IQC-001 Investigating Out of Specification (OOS) and Out of Trend (OOT) Test Results

4.59 SOP IQC-002 Stability Program

4.60 SOP IQC-003 Standard Procedure for Sample Management in Analytical Development and Quality Control Department

4.61 SOP IQC-004 Handling of Contract Laboratories

4.62 SOP IQC-005 Method Validation / Method Verification Guidelines

4.63 SOP IQC-021 Analytical Method Transfer

4.64 SOP IRA-001 Reporting of Adverse Drug Experiences

4.65 SOP IRA-004 Drug Product Registration Requirements

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4.66 SOP IRA-006 Creating or Changing Drug and Device Product Labeling

4.67 SOP IRA-010 Medical Devices Registration Requirements

4.68 SOP ITD-001 Training System

4.69 SOP IVD-001 Cleaning Validation

4.70 SOP IVD-002 Process Validation

4.71 SOP IVD-003 Swab Procedure

4.72 SOP IVD-007 Heating, Ventilation, and Air Conditioning (HVAC) Validation

4.73 SOP IWH-001 Receiving of Materials and Products

4.74 SOP IWH-004 Storage and Disposal of Manufacturing and Laboratory Waste

4.75 STM IMV-I01 Validation of Bacterial Endotoxin Testing

4.76 STM IMV-I02 Method Validation of Sterility Test

4.77 STM IMV-I03 Suitability of Microbial Enumeration Tests and Tests for Specified Microorganisms

4.78 PLN-I01 Project Plan for BPI Labs

4.79 EOL I-030 503B – Active Raw Materials List – BPI Labs

4.80 EOL I-031 503B – Finished Products Code Number List – BPI Labs, Human Drug Products

4.81 EOL I-033 503B – Inactive Raw Materials List – BPI Labs

4.82 EOL I-036 503B – Miscellaneous List – BPI Labs

4.83 EOL I-037 503B – Packaging Components List – BPI Labs

## 5.0 ATTACHMENTS

Not applicable.

## 6.0 PROCEDURE

6.1 Quality Assurance Activities:

6.1.1 It is the responsibility of the Quality Assurance Control Unit to ensure that Quality System requirements are effectively established and maintained in accordance with 21 CFR parts 210, 211, and 820.

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6.1.1.1 The Quality Assurance Control Unit is comprised of all Quality Assurance (QA) Department members / associates that have authority and responsibility to ensure that Quality System requirements are effectively established and maintained (refer to SOP IQA-013 for details).

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6.1.1.2 All departments are responsible for reviewing assigned Quality System documents such as Standard Operating Procedures (SOP), Forms, Job Descriptions, and Training Curriculum as well as ensure technical documentation is current and accurate.

6.1.1.3 QA department is responsible for ensuring all official documents such as SOP and Batch Records are approved, implemented, and distributed and that all obsolete editions of revised documents are retrieved (refer to SOPs IQA-001 and IQA-002 for details).

6.1.2 It is the responsibility of Quality and Operation Management to ensure all employees are qualified through a combination of training and experience to complete and maintain their assigned responsibilities (refer to SOP ITD-001 for details).

6.1.3 QA is responsible for the sampling and approval or rejection of raw materials (components), containers, closures, in-process materials, packaging materials, labeling, and finished products as per applicable specification (SPC) and respective quality system procedures (refer to SOPs IQA-007 and IQA-011 for details).

6.1.4 Analytical Chemistry Quality Control (QC) and Microbiology (MI) departments are responsible for the testing of raw material and finished products as per applicable SPC. QC and MI will review these results before release of material and products.

6.1.5 Retention of finished product reserve samples for applicable analytical and microbial SPC testing is the responsibility of QA, QC, and MI departments.

6.1.6 The results from environmental monitoring, water system testing, and media fill program are reviewed and scrutinized by QA department (refer to SOPs IMI-020, IGN-019, and IGN-025 for details).

6.1.7 Personnel monitoring is not applicable because of the nature of the manufacturing process.

6.1.7.1 After compounding, human intervention with the drug product and possibility of contamination is limited because of the use of peristaltic pumps, sterilized components, aseptic connections, sterilizing grade in-line filtration, and robotic aseptic filling and stoppering.

6.1.8 All documentation related to the manufacturing, labeling, and packaging operations of a product such as, but not limited to, Master Batch Manufacturing Record, Master Batch Labeling Record, Master Batch Packaging Record, and laboratory analytical reports shall be reviewed thoroughly before a batch is released (refer to SOP IQA-021 for details).

6.1.8.1 It is mandatory that all the data in all documents comply with the established SOP and product applicable SPC.

6.1.9 In the event of non-conformance or incidence, QA department is responsible for facilitating investigation of root cause and implementation of Corrective and Preventive Actions (CAPA) following guidelines of SOPs IGN-001, IQC-001, IMI-003, IMI-034, and IQA-024, among others.

6.1.10 In the event of formal product complaint or adverse event, QA department is responsible for facilitating investigation of root cause and implementation of CAPA following guidelines of SOPs IQA-009 and IRA-001, among others.

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6.2 Facility Design:

6.2.1 The manufacturing facility within 12393 Belcher Road, Suite 450, Largo, Florida is designed to prevent contamination and mix ups, segregate zones of differing cleanliness classification, and facilitate ease of cleaning, maintenance, and operations. Refer to the Project Plan for BPI Labs PLN-I01 for more details.

6.2.1.1 The facility prevents contamination and mix ups by designating areas for specific unit operations for a single product at a time. This is controlled by use of equipment and area labeling, QA line clearance, and Manufacturing Batch Record review.

6.2.2 The facility consists of sealed modular cleanroom walls, ceilings, and walkable ceiling panels to maintain ISO 14644 Class 8 conditions throughout the facility.

6.2.3 Potential risks have been identified and applicable controls have been implemented as per facility design Risk Assessment.

6.2.4 The facility has been qualified through the execution of Performance Qualification Protocol to maintain no less than ISO Class 8 cleanliness by controlling non-viable particulate, viable particulate, number of air changes, and directional airflow in cleanrooms.

6.2.4.1 Clean and ample airflow within the facility is controlled by ensuring all supplies and returns are clear, all HEPA filters are leak tested, and the supply airflow is sufficient for the required number of room changes.

6.2.4.2 Manufacturing Science and Technology (MS) department is responsible for validation, requalification, and calibration of facility control systems (refer to SOP IVD-007 for details).

6.2.5 The facility is designed to aseptically fill and stopper syringe and vial 503B drug products within ISO 5 isolators surrounded by a qualified ISO 8 environment.

6.2.5.1 The temperature, relative humidity, and air pressure differentials of all cleanroom environments are continuously monitored during production and periodically revalidated (refer to SOP IQA-005 for details).

6.2.6 Terminally sterilized 503B products are filled under ISO 5 environment surrounded by ISO 8 environment.

6.2.6.1 Terminal sterilization cycles are validated using appropriate biological indicator challenge for 6-log reduction.

6.2.7 Controls are available to maintain and monitor the facility design including, but not limited to, those documented in SOPs IGN-030, IQA-005, and IMI-020.

6.3 Control Systems and Procedures for Maintaining Suitable Facilities:

6.3.1 The facility is designed to limit the possibility of mix ups and cross contamination by establishing defined areas per unit operation and procedures for personnel flow, material flow, and cleaning (refer to SOPs IGN-017, IGN-018, and IGN-028).

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6.3.2 The possibility of cross contamination of hazardous and non-hazardous drugs is limited by designating separate sampling rooms and equipment for dispensing of different drug types.

6.3.2.1 Hazardous drugs are dispensed within containment and dispensing isolators to prevent cross contamination and ensure the safety of operators.

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6.3.3 Production equipment follow cleaning schedules based on production schedule and Time Limitations.

6.3.3.1 Time Limitations are established for production and cleaning of process equipment and areas (refer to SOP IPD-006).

6.3.4 Processing, non-processing areas, and cleanroom support areas are kept clean and sanitary with cleaning schedule of WFI, disinfectant, and weekly sporicidal cleaning agent (refer to SOPs IGN-027 and IGN-028 for details).

6.3.4.1 Cleaning technicians are required to be trained on and review facility cleaning SOP, with an emphasis on cleaning schedule and rotating use of disinfectant / sporicidal cleaning agents.

6.3.4.2 Cleaning, Use, and Maintenance Logbooks are designated for each area to ensure the facility is being cleaned on the established schedule.

6.3.4.3 As with all received materials, disinfectant / sporicidal cleaning agents are inspected by QA department and verified with applicable SPC.

6.3.5 Temperature, relative humidity (RH), and pressure differentials within the manufacturing facility are maintained by the central heating, ventilation, and air conditioning (HVAC) system and monitored through Building Management System (BMS) to maintain product quality. The BMS provides trend reports of each condition and alerts personnel in case of an excursion (refer to SOP IGN-030).

6.3.5.1 The facility is designed to maintain 20 ± 2°C, less than 60% RH, and pressure differentials across rooms of differing classification.

6.3.5.2 These conditions are continuously monitored during production and are a requirement of room release (refer to SOP IQA-005).

6.3.5.3 In case of an excursion, impact is assessed, and incident is initiated when necessary.

6.3.6 Calibration schedule for critical instruments such as temperature, relative humidity, and pressure differential sensors in processing areas and equipment is maintained by QA and executed by MS (refer to SOP ICB-001).

6.3.7 Water systems (purified water, water for injection, and pure steam) are monitored every day of production and frequently as per applicable SPC (refer to SOP IGN-019).

6.3.7.1 In case of an excursion from the applicable SPC, impact is assessed, and investigation is initiated when necessary.

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6.4 Personnel Qualification:

6.4.1 All personnel involved with the compounding of 503B drug products have been trained on established SOP for the dispensing, mixing, and filtration of compounded sterile products (CSP).

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6.4.2 Training Curriculums (TC) are established for initial and periodic GMP refreshment training of employees. This curriculum includes on-the-job and self-training on general and department specific roles (refer to SOP ITD-001 for details).

6.4.2.1 Prior to engaging in any commercial batch manufacturing, personnel must have completed their initial qualification for the applicable unit operation.

6.4.3 GMP trainers must be qualified through completion of the Qualification Technique (QT) prior to new employee or refreshment training.

6.4.4 Personnel, production process, container / closure type, and production equipment have been challenged through Aseptic Processing Simulation (APS) media fill studies prior to engaging in commercial batch manufacturing (refer to SOP IGN-025).

6.4.4.1 APS media fill studies must be successfully performed in worst case scenarios to validate routine manufacturing parameters.

A. For example, validating the use of one (1) in-line filter during compounding of successful APS media fill study validates the use of two (2) in-line filters during routine manufacturing.

6.5 Environmental and Personnel Monitoring:

6.5.1 Environmental conditions such as temperature, relative humidity, and air pressure differentials are continuously monitored by Building Monitoring System (BMS) (refer to SOPs IGN-030 and IQA-005).

6.5.1.1 BMS creates trends of environmental conditions able to be monitored and reviewed by trained personnel. QA reviews these trends prior to each unit operation room release.

6.5.1.2 Air pressure differential limits ensure that cascading pressure differentials are maintained during compounding of sterile drug products.

6.5.1.3 BMS automatically notifies Management / responsible personnel in the event of an excursion from ideal conditions.

6.5.2 Passive air (settle plate) and active air Environmental Monitoring (EM) are conducted daily during compounding, filling, and sterilization operations. Surface (contact plate) sampling is conducted at the end of operation, prior to cleaning (refer to SOP IMI-020).

6.5.2.1 The procedure, locations, actions limits, and justification of locations for EM are established (refer to SOP IMI-020).

6.5.2.2 The results from EM are completed in the applicable Forms and results are reviewed with the Master Batch Manufacturing Record.

6.5.3 Sampling data is reviewed after each batch and an extensive review is conducted periodically to identify any issues and scrutinize existing procedures.

6.5.3.1 In the event of results near or above action levels, QA department is responsible for facilitating investigation of potential product impact and root cause.

6.5.4 Personnel monitoring is not implemented because of the nature of the production process. Refer to the Project Plan PLN-I01 for BPI Labs for more details.

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6.5.4.1 After compounding, human intervention with the drug product and possibility of contamination is limited because of the use of peristaltic pumps, sterilized components, aseptic connections, sterilizing grade in-line filtration, and robotic aseptic filling and stoppering.

6.5.5 Personnel gowning, sanitation, health habits, and health conditions are controlled and established (refer to SOP IGN-010).

6.5.6 Personnel flow and personal protective equipment requirements within the facility are established (refer to SOP IGN-017). It is the responsibility of Production personnel to follow this procedure and Management's responsibility to ensure this procedure is being followed.

6.5.6.1 These procedures control the safety of operators, cleanliness of processing rooms, and limit the possibility of cross contamination.

6.6 Equipment:

6.6.1 Process equipment used for batch production are qualified for use and calibrated on a scheduled maintained by the QA department (refer to SOP ICB-001).

6.6.1.1 The calibration schedule for production equipment and instruments are maintained by QA department and implemented by Manufacturing Science and Technology (MS) department.

6.6.1.2 Product contact surfaces of production equipment must be certified (i.e., certified 316 stainless steel) as non-reactive, non-adsorptive, and non-additive.

6.6.1.3 All documentation concerning material certification and current calibration performed in-house by MS with executed Form or by a third party is maintained by QA department.

6.6.2 Equipment qualifications and validations are approved by QA and executed by MS through Installation, Operation, and Performance Qualification Protocol.

6.6.3 SOP are established for the set up and operation, cleaning, and maintenance of major production equipment and implemented by Production personnel prior to use.

6.6.4 Production department is responsible for training, review, and execution of production equipment cleaning SOPs.

6.6.4.1 Training Record forms are executed at the time of training and maintained by QA department once complete.

6.6.5 Production department is responsible for the use of Cleaning, Use, and Maintenance logbooks to ensure the status of production equipment prior to use.

6.6.6 Refrigerators, freezers, and incubators are monitored with use of calibrated thermometer and, when applicable, relative humidity sensor.

6.6.7 Single-use disposable utensils and components are used for the dispensing, mixing, filtration, and filling of sterile drug products.

6.6.7.1 Inspection and certificate of analyses are used in the verification of these components prior to use.

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6.6.7.2 Components are inspected for damage or contamination prior to and after use via respective batch record.

6.7 Containers and Closures:

6.7.1 Pharmacist / Product Development / Production identifies vendors and materials required for a new project following SOP IPC-001. Materials can be ordered as samples for trial / experimental use; these materials are unaccounted. Once materials and vendors are identified and approved, a code number is requested per SOP IGN-003.

6.7.2 Upon creation of a code number using the appropriate official list, the following activities are coordinated:

6.7.2.1 Pharmacist / Analytical Research / Quality Control Department generates specification (SPC) and standard test method (STM) following instructions delineated in SOP IQA-025. Refer to Table 1 for suggested specification testing for primary and secondary packaging components.

**Table 1 – Suggested Specification Testing for Containers and Closures**

| Type of Material | Suggested Testing Types |
|---|---|
| Primary Packaging (e.g., vial, syringe, cap, stopper) | Description, Physical Tests, Sterility (if applicable), Endotoxin (if applicable), and Certificate of Compliance Check |
| Secondary Packaging (e.g., carton) | Description (Visual Inspection), Physical Tests |

6.7.2.2 Purchasing Department orders material upon management request following SOP IPC-001.

6.7.3 Warehouse Department receives materials following SOP IWH-001.

6.7.4 QA samples and inspects cGMP materials received following SOP IQA-007. Product Development can use these materials in quarantine for formulation trials only, ensuring sampling has been performed and an identification test has been completed, if required, as a discretion of the user.

6.7.5 Pharmacist / Analytical Research / Quality Control Department tests samples received according to the material specification and standard test method. Full testing is performed for all materials unless vendor has been qualified per SOP IQA-010; if this is the case, reduced testing is coordinated based on the tests specified in the specification. If during testing activities, Analytical Research / Quality Control / Microbiology Department finds that any test does not conform to established specifications, an investigation is performed in accordance with SOPs IQC-001 and IMI-003. Upon testing completion, results and data generated are submitted to Quality Assurance for final disposition.

6.7.5.1 Reduced specification testing is performed for containers and closures as suggested by SOP IQA-010 and applicable packaging component SPC, as seen in Table 2.

**Table 2 – Suggested Reduced Specification Testing for Containers and Closures**

| Type of Material | Suggested Reduced Testing Types |
|---|---|
| Primary Packaging (e.g., vial, syringe, cap, stopper) | Description, Physical Tests, Sterility (if applicable), Endotoxin (if applicable), and Certificate of Compliance Check |
| Secondary Packaging (e.g., carton) | Description (Visual Inspection) |

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6.7.6 In case the Product Development Department needs to use a material that is under testing for a cGMP batch, a conditional release request is coordinated as per SOP IQA-011.

6.7.7 The Quality Assurance Department performs final disposition for materials and assigns a retest date (when applicable) and expiration date once inspection and testing is completed as per SOP IQA-011.

**NOTE: Analytical testing methods for active raw materials are validated / verified by the Pharmacist / Analytical Research / Quality Control / Microbiology Department based on method validation guidelines.**

**NOTE: All formal documents are routed for approval using SOP IQA-001.**

6.7.8 As a general practice, retesting is not performed for containers and closures.

6.7.9 Containers and closures are stored in the climate-controlled warehouse monitored by BMS.

6.7.10 Quality Agreements must be established with each primary container and closure vendor to ensure the quality of the finished drug product.

6.7.10.1 Only pre-sterile ready to use (RTU) containers and closures are used for batch production. Vendors must perform sterilization cycle validation proven by Certificate of Analysis.

6.7.10.2 The primary packaging of pre-sterile containers and closures are only removed in ISO 5 areas once ready to be filled and stoppered.

6.7.11 Vendors of primary and secondary packaging materials are routinely evaluated as per SOP IPC-001.

6.8 Components:

6.8.1 Pharmacist / Product Development / Production identifies vendors and materials required for a new project following SOP IPC-001. Materials can be ordered as samples for trial / experimental use; these materials are unaccounted. Once materials and vendors are identified and approved, a code number is requested per SOP IGN-003.

6.8.2 The Active Pharmaceutical Ingredient (API) must be manufactured by an establishment that is FDA registered. Quality Agreements must be made with the API suppliers to ensure product quality and that FDA establishment registration is maintained.

6.8.3 Upon creation of a code number using the appropriate official list, the following activities are coordinated:

6.8.3.1 Pharmacist / Research and Development (R&D) / QC / MI Department generates SPC and STM following instructions delineated in SOP IQA-025. Refer to Table 3 for suggested SPC testing for active and inactive components.

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**Table 3 – Suggested Specification Testing for Active and Inactive Components**

| Type of Material | Suggested Testing Types |
|---|---|
| Active (e.g., API) | Description, Identification, Loss on Drying (water), Assay, Microbial Enumeration Test, Endotoxin |
| Inactive (e.g., excipient) | Description, Identification, Microbial Enumeration Test (if applicable), Endotoxin (if applicable) |

6.8.3.2 Purchasing Department orders materials upon management request as per SOP IPC-001.

6.8.4 Warehouse Department receives materials as per SOP IWH-001.

6.8.5 Active and inactive pharmaceutical ingredients are stored in the climate-controlled warehouse monitored by BMS.

6.8.6 QA Department samples and inspects cGMP materials received as per IQA-007. Pharmacist / Product Development can use these materials in quarantine for formulation trials only, ensuring sampling has been performed and an identification test has been completed, if required, as a discretion of the user.

6.8.6.1 Sampling is conducted within the manufacturing facility with use of complete gowning, Personal Protective Equipment (PPE), and dispensing hood or isolator.

6.8.7 Cleaning validation is not performed for components because of the use of single use systems.

6.8.8 Pharmacist / Analytical Research / Quality Control Department tests samples received according to the material specification and standard test method. Full testing is performed for all materials unless vendor has been qualified per SOP IQA-010; if this is the case, reduced testing is coordinated based on the tests specified in the specification. If during testing activities, Analytical Research / Quality Control / Microbiology Department finds that any test does not conform to established specifications, an investigation is performed in accordance with SOPs IQC-001 and IMI-003. Upon testing completion, results and data generated are submitted to Quality Assurance for final disposition.

6.8.8.1 Reduced specification testing is performed for active and inactive pharmaceutical ingredients as suggested by SOP IQA-010 and applicable packaging component SPC, as seen in Table 4.

**Table 4 – Suggested Reduced Specification Testing for Active and Inactive Components**

| Type of Material | Suggested Reduced Testing Types |
|---|---|
| Active (e.g., API) | Description, Identification, Loss on Drying (water), Assay, Microbial Enumeration Test (if applicable), Endotoxin (if applicable) |
| Inactive (e.g., excipient) | Description, Identification, Microbial Enumeration Test (if applicable), Endotoxin (if applicable) |

6.8.9 In case the Product Development Department needs to use a material that is under testing for a cGMP batch, a conditional release request is coordinated as per SOP IQA-011.

6.8.10 The Quality Assurance Department performs final disposition for materials and assigns a retest date (when applicable) and expiration date once inspection and testing is completed as per SOP IQA-011.

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**NOTE: Analytical testing methods for active raw materials are validated / verified by the QC / MI Department based on method validation guidelines.**

**NOTE: All formal documents are routed for approval through Change Control System.**

6.8.11 Retesting is performed for active and inactive components as per SOP IQA-012.

6.8.12 Vendor of active and inactive materials are routinely evaluated as per SOP IPC-001 (i.e., active materials ever year and inactive materials every two years).

6.9 Production and Process Controls:

6.9.1 General Controls:

6.9.1.1 Master batch records prepared for R&D products, proposed commercial products, and scale-up/validation/commercial product products are prepared by Product Development, Pharmacist, and/or Production department.

A. Master batch and packaging records for 503B products should be prepared as per SOP IGN-023.

6.9.1.2 All master batch and packaging records must be reviewed by Pharmacist / Production / Product Development departments and approved by Regulatory Affairs and QA departments.

6.9.1.3 All batch and packaging records are requested by Production designee and issued by QA department as per SOP IQA-006.

6.9.1.4 It is the responsibility of Production department to request room release per production unit operation and the responsibility of QA department to follow clearance procedure as per SOP IQA-014.

6.9.1.5 Time Limitations (refer to SOP IPD-006) and Hold Times must be followed for production process and in-process product as validated through media fill validation program.

A. The storage time limitation of bulk solution is validated through successful results of Hold Time study protocol.

6.9.1.6 503B drug products are aseptically handled by use of peristaltic pumps, aseptic connections, and pre-sterile components, among others.

6.9.1.7 Terminally sterilized 503B products are filled under ISO 5 environment surrounded by ISO 8 environment.

A. Terminal sterilization cycles are validated using appropriate biological indicator challenge for 6-log reduction.

6.9.1.8 Production parameters such as production equipment, process parameters, hold times, and time limitations or validated under worst-case scenario simulation during media fill validation program.

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6.9.2 General Production Process:

6.9.2.1 503B manufacturing and packaging operations follow the general production process of documentation release, line clearance, weigh and dispense, mixing, filtration, filling, terminal sterilization (when applicable), packaging, and labeling.

6.9.2.2 Documentation such as batch manufacturing record and applicable forms are requested by Production designee and issued by QA department as per IQA-006.

6.9.2.3 Line clearance / room release is requested by Production department prior to each operation and issued by QA department as per SOP IQA-014.

6.9.2.4 Weighing and dispensing of raw pharmaceutical ingredients (e.g., API, excipient) is performed by use of restricted access isolator or dispensing hoods as per batch record and SOP IPD-002.

6.9.2.5 Raw pharmaceutical ingredients are mixed with pharmaceutical grade Water for Injection (WFI) as per batch record.

6.9.2.6 Mixed unfiltered intermediate product is aseptically filtered by use of sterilizing grade filters into pre-sterile fill path or intermediate bags.

6.9.2.7 Filters used during filtration are sterilizing grade 0.2µ hydrophilic filters. 100% of filters used for batch manufacturing are filter integrity tested, with the results from these tests included within the Batch Manufacturing Record.

6.9.2.8 Filling will occur within controlled ISO 5 environment surrounded by ISO 8 environment.

6.9.2.9 When applicable, terminal sterilization will be performed by use of validated cycle and qualified equipment.

6.9.2.10 Packaging and labeling operation is performed as per packaging record and SOPs IPK-001 and IPK-002.

6.9.3 Research and Development Products:

6.9.3.1 Pharmacist identifies new projects to be developed in the company based on, but not limited to, company and marketing needs, and opportunities nominated by FDA "Bulk Drug Substances Nominated for use in Compounding under Section 503B of Food, Drug, and Cosmetic Act".

6.9.3.2 Pharmacist shall use SOP IPH-002 to determine if the proposed new project is essentially a copy of an approved or unapproved drug product. New projects shall be in compliance with "FDA Guidance for Industry Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act".

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6.9.3.3 Pharmacist / Product Development Department prepares the marketing trade dress for the project with the purpose of understanding all aspects of the formulation, process, and labeling, among others, of the product. Pharmacist / Product Development Department prepares the R&D checklists for covering project planning and execution activities and ensuring that all project activities have been completed and that the FDA expectations, needs, and requirements have been met.

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6.9.3.4 Pharmacist designs experimental batches in order to analyze product behavior and test different formulations and processes (refer to SOP IPH-001 for details). Generally, these batches are documented and tracked via notebook. At this stage, Pharmacist / R&D / QC Department can analyze experimental samples and coordinate informal stability of the product. All experimental data generated by the Laboratory is submitted to the Pharmacist / Product Development Department for analysis and further action. Experimental batches are disposed according applicable SOP when required.

6.9.3.5 QA Validation Department incorporates the product into the cleaning validation matrix in order to swab cGMP equipment to look for active residue content (if equipment is shared between products). Pharmacist / R&D / QC Department prepares documented method in the laboratory to analyze active residue content of swab samples (refer to SOPs IVD-001, IVD-003, and IQC-005), when applicable.

6.9.3.6 QA Department swabs product contact cGMP equipment following cleaning validation matrix and submits swab samples to R&D / QC Department for analysis as per SOPs IVD-001 and IVD-003.

6.9.3.7 Once Pharmacist / Product Development develops the formulation and processes that are going to be used in the manufacturing of the product for stability / Beyond-use-Dating (BUD) or batch, a code number is requested via SOP IGN-003.

6.9.3.8 Upon creation of code number using the appropriate official list, the following activities are coordinated:

A. Pharmacist / R&D / QC Department generates specification for intermediates and bulk finished products, and STM (refer to SOP IQA-025 for details).

B. Pharmacist / Product Development prepares master batch records and master packaging records for stability batches, ensuring formula number is traceable. The sampling plan requirements are included as part of the master batch records and master packaging records where all instructions are clearly sequentially identified and step by step process is implemented and executed at all times (refer to SOP IGN-023 for details).

C. Pharmacist / R&D / QC / Microbiology Department coordinates method validation of analytical, microbial testing (i.e., Description, Assay, Sterility, Bacterial Endotoxins Test) only for stability products (refer to STMs IMV-I01 and IMV-I02 as well as SOP IQC-005).

6.9.3.9 Pharmacist / Production requests issuance of master batch record and executes batch using a cGMP qualified and validated facility and equipment. Samples of the intermediate and bulk finished products are submitted to Pharmacist / R&D / QC Department for testing. If during testing activities Pharmacist / R&D / QC Department finds that any test does not conform to established specifications, an investigation is performed. Upon testing completion, results and data generated are submitted to QA for final disposition.

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6.9.3.10 Pharmacist / Production submits executed batch record to QA Department for review and final disposition.

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6.9.3.11 Pharmacist / Production requests conditional release of the Bulk Finished Product to QA before packaging operation in case final disposition has not been determined by QA at the time of performing the packaging operation.

6.9.3.12 Pharmacist / Production requests issuance of master packaging record, executes a batch using a cGMP qualified and validated facility and equipment, and submits executed packaging record to QA Department for final disposition.

6.9.4 Scale-up of Products:

6.9.4.1 Pharmacist with the help of Production coordinates the scale-up activities (when required) and prepares the commercial master batch record and the master packaging record (ensuring formula number is traceable with stability batch).

6.9.4.2 Pharmacist / R&D / QC Department coordinates method transfer of the analytical testing during the scale-up activities, if required (refer to SOP IQC-021).

6.9.4.3 The QA Department prepares cleaning validation protocol to be executed accordingly, if necessary (refer to SOP IVD-001 for details).

6.9.4.4 QA Department coordinates preparation of Stability Protocol for commercial batches (refer to SOP IQC-002 for details).

6.9.4.5 Labeling group or designee coordinates preparation of printed labeling material (i.e., product label) to be used in the commercial products (refer to SOP IRA-006 for details).

**NOTE: Product checklist is prepared to plan and execute all activities related to the commercial launch.**

6.9.5 Validation of Commercial Products:

6.9.5.1 Pharmacist / Production Department requests issuance of commercial master batch records, commercial master packaging records, and process validation protocols (refer to SOP IVD-002 for details).

6.9.5.2 Pharmacist / Production Department with the help of Pharmacist and QA Department executes data requested usually in the first batch using a cGMP qualified and validated facility and equipment.

6.9.6 Commercial Products:

6.9.6.1 Production Department executes validated product and processes based on production schedule using cGMP qualified and validated facility and equipment.

6.9.6.2 Product contact components (filters, tubing, aseptic connections, fill path) are sterilized by use of validated cycles.

A. In-house sterilization cycle validation is performed by use of Biological Indicators (BI) and calibrated thermocouples. The sterilization time of these validated cycles are increased for routine manufacturing overkill potential.

B. Product container / closure are pre-sterile and sealed components sterilized with validated cycles by the manufacturer.

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6.9.6.3 The details (BPI receiving number, expiration date, etc.) of each component used in batch manufacturing are logged within Master Batch Manufacturing Record.

A. These details include the expiration date for depyrogenated glassware (vials, syringes, etc.) used in the manufacture of a batch.

6.9.6.4 Upon completion of the batch, the finished drug product will remain in quarantine until being released through inspection, testing, and release facilitated by QA.

A. Visual inspection is conducted by qualified individuals who undergo annual eye exams to ensure 20/20 vision (refer to SOP IPD-007).

6.9.6.5 QA Department reviews all data generated including Master Batch Manufacturing Record and analytical testing from the commercial batches and performs final disposition of each batch before distribution (refer to SOPs IQA-011 and IQA-021).

A. Complete records are maintained with Quality Assurance Control Unit's Document Control (refer to SOP IQA-002).

6.9.6.6 In the event of non-conformance or incidence, QA department is responsible for facilitating investigation of root cause and implementation of Corrective and Preventive Actions (CAPA) following guidelines of SOPs IGN-001, IQC-001, IMI-003, and IQA-024, among others.

6.10 Release Testing:

6.10.1 Specification for each finished 503B drug product is created as per SOP IQA-025 to ensure finished drug product quality.

6.10.2 Generally, product specific SPC tests include chemical, microbial, and physical tests listed in Table 5.

**Table 5 - General Release Specification Testing for 503B Finished Drug Products**

| Test | Specification |
|---|---|
| Description | As per applicable SPC |
| Identification A (by HPLC) | As per applicable SPC |
| pH <USP 791> | As per applicable SPC |
| Container Content USP <697> | As per applicable SPC |
| Particulate Matter USP <1> | Foreign matter (Visible particulates): Free from foreign matter. |
| | Subvisible Particles USP <788><br>Particles ≥ 10µm: NMT 6000 per container<br>Particles ≥ 25µm: NMT 600 per container |
| Assay | As per applicable SPC |
| Bacterial Endotoxins Test USP <85> | As per applicable SPC |
| Sterility Tests USP <71> | No evidence of microbial growth |

6.10.3 Antimicrobial effectiveness test is only performed as necessary for 503B drug products labeled as multiple dose.

6.10.4 Product specification testing may be outsourced to contract laboratory, as needed as per IQC-004.

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6.10.5 Prior to product release, it is the responsibility of Pharmacist and QA department to review the executed batch records, microbial environmental monitoring results, and finished product testing results as per SOP IQA-021.

6.10.6 Specification test results are reviewed and finished 503B drug products are released as per SOP IQA-011.

6.11 Laboratory Controls:

6.11.1 Sampling of raw material and finished products is conducted by QA department.

6.11.2 Testing is conducted by QC and MI departments as per product / material specific validated standard test method (STM) and specification (SPC) criteria.

6.11.3 Clear and complete records of laboratory data is kept in laboratory notebook, analytical worksheet, reports, and logbooks for QC, R&D, and MI Departments.

6.11.4 United States Pharmacopoeia (USP) and European Pharmacopoeia (EP) standards are followed for the procedure of preparation, qualification, storage, handling, and use of laboratory analytical standards.

6.11.5 The procedure for approval of contract laboratories, receiving and shipping of samples, coordination of testing, receiving of results and submission of data to QA department is established by SOP IQC-004.

6.11.5.1 Contract laboratory is a BPI qualified and FDA approved independent company that has entered into a Quality Agreement with BPI to test pharmaceutical products such as raw material, in-process samples, and finished products.

A. Quality Agreements are established as per FDA Guidance Contract Manufacturing Agreements for Drugs: Quality Agreements and ISO 17025.

6.11.5.2 Pharmacist / QC department is responsible for reviewing the data for accuracy, completing analytical report and specification, and submitting analytical report to QA department.

6.11.5.3 QA department is responsible for final disposition of product based on the received results.

6.12 Stability / Expiration Dating for Compounded Drug Products:

6.12.1 The expiration date for all products, is established through the conduct of a stability program that includes testing to assess the product's performance against specifications after aging to the desired expiration date (§ 211.137); the conditions are outlined in ICH guidance for industry 4 Q1A(R2) Stability Testing of New Drug Substances and Products.

6.12.1.1 Beyond use Date (BUD), like expiration date, is the number of days or date at which a drug product is no longer acceptable for use. BUD is calculated from the date of manufacture (i.e., compounding date).

6.12.2 The expiration date is presented as month/date/year using the format MM/DD/YY (i.e., 08/20/19) or equivalent.

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6.12.3 A listing of established products and their corresponding expiration dating intervals is included in Finished Products Code Number List.

6.12.4 The expiration dating interval is established by obtaining stability data conducted by following an established stability protocol specific for the product (refer to SOP IQC-002 for additional details), as per SOP IQA-019 assignment of expiration dates are given, within requirements listed below.

6.12.4.1 At least 10 percent of the proposed maximum size commercial batch (i.e., pilot scale size) or at least commercial batch size.

6.12.4.2 Stability study condition and test intervals can be found in Table 6.

**NOTE: As a general policy, Accelerated (AA) stability studies are only conducted for Stability batches. Long Term (CRT) stability studies are conducted for Stability and Commercial batches.**

**Table 6 - Temperature, Relative Humidity, Test Interval Conditions for Stability Studies**

| | Temperature | Relative Humidity | Test Intervals |
|---|---|---|---|
| **Long Term (CRT)** | 25°C ± 2°C | 60%RH ± 5%RH | 2, 4, 6, 8 months |
| **Accelerated (AA)** | 40°C ± 2°C | 75%RH ± 5%RH | 1, 2 months |

6.12.4.3 Accelerated studies, combined with basic information of the components, drug products, and container / closure system, may be used to establish a tentative BUD interval provided shelf life studies are not available and are being conducted.

6.12.4.4 For product stored in accelerated conditions that yield acceptable stability results after 30 days (1 month), BUD / expiration dating interval of 240 days (8 months) from the manufacturing date of the batch can be assigned.

Example: If the batch was manufactured on 08/20/19 and stability data shows that the product is stable for 30 days in the accelerated conditions, a tentative BUD/expiration date of 04/15/20 can be assigned to the product, as follows.

Manufacturing Date (Compounding Date): 08/20/19

Beyond Use Date Interval: 240 days

Beyond Use Date (BUD): 08/20/19 + 240 days - 1 day = 04/15/20

**NOTE: In case the BUD / expiration dating interval is assigned as 360 days, then the test intervals for the long term stability are adjusted accordingly, i.e., 3, 6, 9, and 12 months.**

6.12.4.5 When a tentative expiration dating interval has been established using accelerated test data and the product has been marketed based on that interval, if the product stored at a controlled room temperature fails to conform to all acceptance criteria during stability testing, an investigation is conducted following SOP IGN-001.

6.12.4.6 All official data generated in the development phase is filed by Document Control.

**NOTE: Preparation and approval activities of all formal documents are performed using Change Control System.**

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6.12.4.7 All data generated from the validation including analytical testing are submitted to QA for final disposition and assignment of beyond use date (BUD) based on results of stability data.

6.13 Packaging and Labels:

6.13.1 All units should be packaged and labeled in accordance with SOPs IPK-001 and IPK-002 as well as Master Batch Packaging Record created in Quality System as per SOP IGN-023.

6.13.1.1 Product labels and Master Batch Packaging Record are controlled and released by QA department as per SOP IQA-006.

6.13.2 Labels must contain the following information:

6.13.2.1 The statement: "This is a compounded drug." Or a reasonable comparable alternative statement that prominently identifies the drug as a compounded drug.

6.13.2.2 Name, address, and phone number of the facility.

6.13.2.3 The statement: "Rx Only."

6.13.2.4 The following details of the drug:

A. Established name.
B. Quantity or volume, dosage form, and strength.
C. The date the drug was compounded.
D. Expiration or beyond use date.
E. Lot or Batch Number.
F. Storage and handling instructions.
G. National Drug Code Number (NDC No.) when available.
H. The statement "Not for resale", and, if the drug is dispensed or distributed other than pursuant to a prescription for an individually identified patient, the statement "Office Use Only".
I. A list of active and inactive ingredients identified by established name and the quantity or proportion of each ingredient.

6.13.2.5 FDA website and phone number: "www.fda.gov/medwatch" and "1-800-FDA-1088".

6.13.3 Labeling operation is performed in-house either manually or with use of automated labeler.

6.13.3.1 A specimen label is placed in the master labeling batch record for reference prior to Labeling operation.

6.13.3.2 Labels are placed on the units and labeled units are inspected throughout labeling process as per Master Batch Labeling Record.

6.13.3.3 Labeled units are placed in trays and trays are labeled with "STATUS" label.

**NOTE: Serialization as per SOP IGN-036 is not applicable for 503B drug products.**

6.13.4 Packaging operation is performed in-house or by an outside packaging contractor.

6.13.4.1 In-house, labeled units will be manually placed in carton holders, filled carton holders will be placed into cartons, and filled cartons will be manually placed into shipping boxes.

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6.13.4.2 This series of packaging containers as well as labeling equipment inspection ensures stability of containers, prevents mix-up, mechanical abrasion to product containers, and possible product contamination.

6.13.4.3 Unlabeled product or "brite stock" can be stored into inventory for future labeling and packaging (refer to SOP IPK-003 for details).

6.13.5 When labeling process is complete, a reconciliation of the used filled product, labeling materials, and labeling units is performed as per Master Batch Labeling Record.

6.13.5.1 Discrepancies during reconciliation are investigated as per SOP IGN-001.

6.13.5.2 Excess of labels with Lot and control numbers printed are destroyed.

6.14 Reserve Samples:

6.14.1 Retention samples will be taken for each batch of 503B product inline with guidelines included in SOP IQA-020.

6.14.2 As a general practice, the quantity of the retention sample is determined to cover no less than twice the quantity necessary for all analytical and microbial tests as per the applicable specification. The quantity of the retention sample for each product is listed in applicable EOL.

6.14.3 Reserve samples must be retained and stored under the labeled storage conditions and in the same immediate container-closure system in which the drug product is marketed or in one that has essentially the same characteristics (e.g., same material, same headspace for liquids).

6.14.4 Reserve samples must be held for no less than 30 days following the established expiration date.

6.14.5 Reserve samples are collected from the beginning, middle, and end of a packaging run.

6.14.6 Generally, QA department pulls retention samples of packaged product according SOP IQA-020.

6.15 Product Complaint Handling:

6.15.1 The procedure to handle (receipt, logging, investigation, monitoring, trending, and resolution) written and oral product complaints received by the company concerning any of the distributed drug products is established as per SOP IQA-009.

6.15.2 All complaints received are logged into "Complaints" logbook and assigned a complaint number.

6.15.3 Depending on the nature of the complaint, QA or designee may request concerned department for investigation, along with complaint sample if available.

6.15.4 QA or designee will investigate through review of batch record, packaging record, and analytical data looking for deviations, issues, or nonconformance to evaluate the impact and cause of the complaint.

6.15.5 QA or designee will arrange for appropriate physical, chemical, and/or microbial testing of complaint sample.

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6.15.6 Once the results are reviewed, an Investigation report is prepared indicating the detailed investigation, most probable root cause, corrective and preventive actions, and conclusions. Corrective and preventive actions are addressed as per applicable SOP.

6.16 Adverse Event Handling:

6.16.1 The procedure for the surveillance, receipt, evaluation, and reporting of Adverse Drug Experiences (ADEs) associated with human and veterinary drug products manufactured at BPI Labs must follow the FDA guideline "Adverse Event Reporting for Outsourcing Facilities under Section 503B of the Federal Food, Drug, and Cosmetic Act".

6.16.2 It is the responsibility of Regulatory Affairs personnel to assure all ADEs (i.e., all serious and unexpected adverse drug experiences) are properly documented, investigated by appropriate personnel, and reported to the FDA (i.e., 15-day Alert Report) as per SOP IRA-001.

6.16.3 Regulation requires reporting of each ADE as soon as possible, but in no case later than 15 calendar days from initial receipt.

6.16.4 All reported ADE must be promptly investigated and a follow-up report must be submitted within 15 calendar days of receipt of new information or as requested by the FDA. If additional information is not obtainable, records should be maintained of the unsuccessful steps taken to seek additional information.

6.16.5 Reports to the FDA concerning ADE must include pertinent identifying details:

6.16.5.1 An identifiable patient.

A. Information on the names and addresses of patients should not be included. A unique code should be assigned for each individual patient.

6.16.5.2 An identifiable reporter.

A. Defined as a patient, consumer, family member, doctor, pharmacist, other health care professional or related individual.
B. A reporter can be identified by one or more of the following: personal identifier (e.g., name), professional identifier (e.g., doctor, nurse, pharmacist), contact information (e.g., e-mail address, phone number).

6.16.5.3 A suspect drug product.

A. Defined as a product suspected as associated with the adverse event.
B. In the case that an adverse event involves multiple suspect drug products compounded by the same facility, the facility should only submit one report with all drug products listed.

6.16.5.4 A serious adverse event.

A. Defined as a patient outcome involving death, life-threatening ADE, inpatient hospitalization, disability or incapacity, or a congenital anomaly or birth defect.

6.16.6 Reports must be submitted with current labeling of drug product, hospital summaries, autopsy/death certificate, relevant laboratory data, and clinical data.

6.16.7 Reports can be submitted through the Safety Reporting Portal (SRP) or the Electronic Submissions Gateway (ESG).

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6.16.8 Before submitting electronically for the first time, facilities should notify the FDA Adverse Event Reporting System (FAERS) Electronic Submission Coordinator to assist the facility in its submission.

6.16.9 Regulations require firms to maintain records relating to all ADEs (including raw data and any correspondence relating to the adverse drug experiences) for no less than 10 years and to permit any authorized FDA employee, at all reasonable times, to have access to and copy and verify the records established and maintained under 21 CFR Part 310.305.

6.17 Regulatory Requirements:

6.17.1 Registration with FDA:

6.17.1.1 Refer to the FDA Guidance "Registration of Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act" for all suggestions regarding electronic 503B registration with the FDA.

6.17.1.2 Outsourcing facilities must register initially and each year thereafter during the registration period between October 1st and December 31st.

6.17.1.3 To register as an outsourcing facility, a compounder must provide the following information:

A. Name
B. Place of business.
C. Unique facility identifier.
D. Point of contact email address.
E. Indication whether the facility intends to compound products on FDA's drug shortage list.
F. Indication whether the facility compounds from bulk drug substances, and if so, whether it compounds sterile or nonsterile drugs from bulk drug substances.

6.17.1.4 Facilities intending to register as outsourcing facilities should submit registration using existing Structured Product Labeling (SPL) format.

A. Refer to Section IV of FDA Guidance "Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing" for complete details for SPL submission.

6.17.1.5 FDA is required to publish a list of registered outsourcing facilities and the facilities' status, as well as, update the list weekly.

6.17.2 Registration with Florida Department of Health Board of Pharmacy:

6.17.2.1 Refer to Rule 64B16-28.100 "Special Sterile Compounding Permit Application and Information" for a complete guidance on application and permitting requirements for special compounding facilities established by Florida Department of Health under Florida Statute Chapter 465.

6.17.2.2 Permits are only valid for the name and physical location to which it is issued. Any changes to facility name or location must be requested through Florida Department of Health Board of Pharmacy.

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6.17.2.3 An initial onsite inspection is required for issuance of a new permit. The board inspector will document the facility's compliance with all applicable rules and statues.

6.17.2.4 Outsourcing facilities engaged in sterile compounding must obtain and maintain a Special Sterile Compounding Permit by filing an application with form DH-MQA 1270 "Special Sterile Compounding Permit Application and Information".

6.17.2.5 Applicants for a Special Sterile Compounding Permit must comply with all permitting requirements in subsection (1) of Rule 64B16-28.100 and designate a prescription department manager or consultant pharmacist on record.

6.17.2.6 Florida Department of Health reserves the right to inspect outsourcing facilities at any time after the initial inspection.

6.17.3 Reporting to FDA:

6.17.3.1 Outsourcing facilities must submit a product report upon initial registration and twice each year thereafter, once in June and once in December, for products produced during the previous six-month period.

A. Drug product reports submitted between June 1 and June 30 of each year must report products produced from December 1 through May 31.

B. Drug product reports submitted between December 1 and December 30 of each year must report products produced from June 1 through November 30.

6.17.3.2 Each semiannual report must identify all sterile and non-sterile drugs compounded at the outsourcing facility during the previous six-month period and provide the following information for each compounded drug:

A. The active ingredient and strength of active ingredient per unit.
B. The source of the active ingredient.
C. The 10-digit National Drug Code (NDC) number of the source drug or bulk active ingredient, if available.
D. The dosage form and route of administration.
E. The package description.
F. The number of individual units produced.
G. The 10-digit NDC number of the final product, if assigned.

6.17.3.3 Outsourcing facilities must submit drug product reporting electronically in SPL format. Refer to FDA guidance "Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food Drug and Cosmetic Act" for more information about drug product reporting.

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|---|---|---|
| IGN-033 | HANDLING OF 503B PRODUCTS | 08 |

## 7.0 REVISION HISTORY

| Revision No. | Effective Date | Description of Changes |
|---|---|---|
| 01 | AUG 29 2019 | Original SOP |
| 02 | OCT 02 2019 | Section 4.39 SOP No. IPT-006 503B Research and Development Experimental Trial Batches updated to new SOP No. IPH-001 503B Research and Development Experimental Trial Batches.<br><br>Section 6.9.3.2 SOP No. IPT-006 503B Research and Development Experimental Trial Batches updated to new SOP No. IPH-001 503B Research and Development Experimental Trial Batches.<br><br>Sections 6.4.4, 6.4.5, and 6.5.3 Removed from SOP, redundancy |
| 03 | NOV 27 2019 | Section 6.12 Table 6 to Include 9 Month Long Term Testing Interval, and 2 Month Accelerated Testing Interval.<br><br>Section 6.12.4.4 to change expiration dating to 240 days (8 months), and tentative BUD date to 04/15/20. |
| 04 | MAY 12 2020 | A note added under Section 6.12.4.2.<br>Section 6.12 Table 6 to replace 9 Month Long Term Testing Interval with 8 Month Long Term Testing Interval. |
| 05 | JAN 22 2021 | Added References SOPs GN-040 "Handling of 503 Products" and IQA-012 "Retesting of Materials and Products"<br><br>Minor editorial changes to Purpose, Scope, and Sections 6.1.4, 6.9.2.3, and 6.15.2 |
| 06 | APR 28 2021 | Added References SOP IPH-002 BPI Policy for Essentially Copies of Approved Drug Products.<br><br>Section 6.9.3.2 changed to discuss use of new SOP IPH-002. Section numbering is modified to reflect this change. |
| 07 | MAY 06 2021 | 1. Add 21 CFR Part 310 – New Drugs, Subpart D – Records and Reports, Section 310.305 in the Reference section.<br>2. Section 6.8.2 updated to reflect FDA establishment registration for APIs.<br>3. Revise SOP Section 6.16 to clarify the reporting and handling of ADEs according to 21 CFR Part 310.305. |
| 08 | AUG 3 1 2021 | Clarify Section 6.12.4.4 in regards to BUD calculation and stability test intervals for long term in case of 360 days BUD interval. |

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| | Category: BPI SOP<br>Title: IGN-033 Handling of 503B Products | | |
|---|---|---|---|
| **Version**<br>01 | **State**<br>Effective | **Effective Date**<br>29-MAR-2023 | **Document ID**<br>834697 |



## REVISION HISTORY

**Version 01 Effective on 29-Mar-2023**
Initial Migration

## DOCUMENT ELECTRONIC SIGNATURES

### DOCUMENT APPROVAL WORKFLOW

**Author Approval**

ZenQMS System

This document was an already EFFECTIVE document that was migrated from legacy systems on this date.
*Signed 10:52:44 PM UTC 03-Apr-2023*

| SOP No. | Title | Revision No. |
|---|---|---|
| IGN-028 | CLEANING OF PROCESSING AND NON-PROCESSING ROOMS | 08 |

| Prepared By / Date | Reviewed By / Date | QA Approved By / Date | Effective Date |
|---|---|---|---|
| PHK 01/20/23 | 01/22/23 | M. Salazar 01/23/23 | JAN 27 2023 |
| | | | Change Control No. |
| Title: Manager. | Title: COO | Title: CQCO | I-23027 |

## 1.0 PURPOSE

The purpose of this SOP is to describe procedures for cleaning of the manufacturing processing and non-processing rooms, including cleanroom support areas, laboratories, warehouse, and utility areas.

## 2.0 SCOPE

This procedure is applicable for the cleaning of processing areas (such as samples, formulations, and filling), non-processing areas (such as utility areas, non-cleanroom corridors, laboratories, warehouse, and change rooms), and cleanroom support areas (such as cleanroom corridors, clean equipment room, and cleaning supplies room) located in BPI Labs.

## 3.0 RESPONSIBILITY

It is the responsibility of the Production Cleaner to follow this procedure and it is the responsibility of the Production / Laboratory Manager or designee to implement and monitor the procedure.

## 4.0 REFERENCES

4.1 21 CFR Part 211.42 Design and Construction Features

4.2 21 CFR Part 211.56 Sanitation

4.3 USP <1072> Disinfectants and Antiseptics

4.4 USFDA Guidance for Industry Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice

4.5 PDA Technical Report 70 Fundamentals of Cleaning and Disinfection Programs for Aseptic Manufacturing Facilities

4.6 SOP IGN-027 Preparation of Cleaning Agents, Detergents, and Disinfectants Used in Manufacturing

4.7 EOL I-003 Miscellaneous List

## 5.0 ATTACHMENTS

Not Applicable.

## 6.0 PROCEDURE

6.1 General Requirement:

6.1.1 When performing cleaning, ensure hazardous energy sources are tagged and locked out.

6.1.2 Review the applicable SDS for handling, instructions, personal protective equipment requirements, and disposal instructions for any chemicals and materials involved in this process.

6.1.3 Use gloves, masks, and safety goggles / face shields while cleaning.

**NOTE: After shut-down activities, all rooms must be cleaned as per procedure mentioned in Weekly Cleaning (steps 6.3.9) before being utilized.**

6.1.4 All areas under the scope of this SOP are listed in Table 1 below.

**Table 1: Processing, Non-Processing, and Cleanroom Support Areas**

| Processing Areas | Non-Processing Areas |
|---|---|
| Filling Rooms (Rooms 312 and 317) | Non-Cleanroom Corridors (Corridors 201, 207, and 409) |
| Formulation Rooms (Rooms 311 and 316) | Change Rooms / Lockers (Rooms 202 and 203) |
| Autoclave Load (Room 313) | Quality Control Laboratory (Rooms 103, 104, and 107) |
| Autoclave Unload (Room 319) | Microbiology Laboratory (Room 205) |
| Tank WIP Room (Room 315) | MLT Laboratory (Room 211) |
| Samples Rooms (Rooms 308 and 308A) | Warehouse (Shipping and Receiving) (Rooms 408 and 411) |
| Sterility Isolator Room (Room 210) | Utility Area / Boiler Room (Rooms 403 and 404) |
| **Cleanroom Support Areas** | Tech Space (Room 208) |
| Cleanroom Corridors (Corridors 310 and 301) | Vestibule (Room 101) |
| Personnel Gowning Airlock (Room 304) | Restrooms (Rooms 105 and 106) |
| Personnel De-Gowning Airlock (Room 303) | Inspection and Packaging Rooms (Rooms 405 and 407) |
| Material Airlocks (Rooms 305, 306, and 309) | Labeling and Packaging Room (Room 412) |
| Clean Equipment Room (Room 318) | |
| Component Preparation Room (Room 314) | |
| Cleaning Supplies Room (Room 302) | |
| Anteroom (Room 204) | |
| Airlocks (Rooms 307 and 209) | |

6.1.5 Types of Areas:

6.1.5.1 Processing Areas include rooms in cleanroom area that may be used for Production.

6.1.5.2 Cleanroom Support Areas include rooms and corridors that are within cleanroom area but where a Production process would not occur.

6.1.5.3 Non-Processing Areas are rooms and corridors outside the cleanroom area, and where open product would not be exposed.

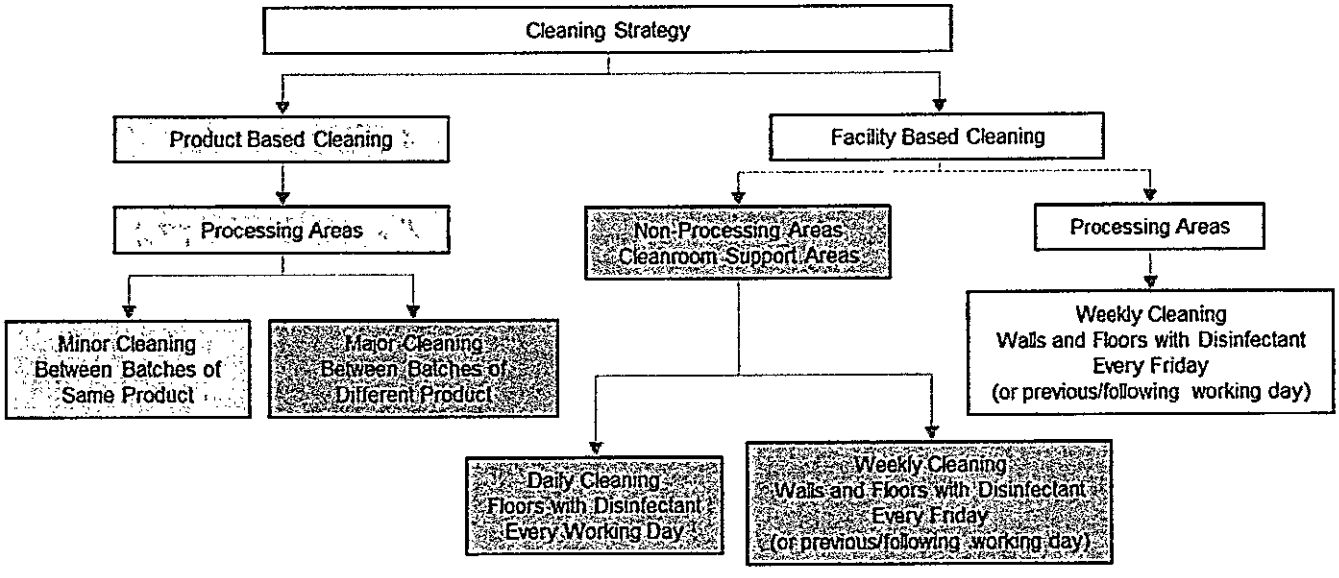
A. Inspection and Packaging Rooms and Labeling and Packaging Room are areas outside the cleanroom where Finished Product is processed, but always in a sterile, sealed state. As there is no open product, routine Facility Based Cleaning is

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performed as per Table 4 and Product Based Cleaning is performed as per Step 6.2.5.

6.1.6 BPI's cleaning strategy is designed considering cross contamination and microbial bioburden. Product Based Cleaning revolves around manufacturing areas and reducing the risk of contamination of the product. Facility Based Cleaning involves areas of all classifications and ensuring there is no introduction of microbial contaminants from lower to higher classified areas. See Figure 1 below.

**Figure 1: Cleaning Strategy Flow**




6.1.7 Cleaning Strategy:

6.1.7.1 Mops and cleaning supplies used in Non-Processing Areas will NOT be used in Processing Areas or Cleanroom Support Areas, however the same mops and cleaning supplies can be used between Processing Areas and Cleanroom Support Areas. Ensure mops and cleaning supplies are labeled accordingly.

6.1.7.2 Ensure the correct cleaning supplies are used for their respective area by reviewing the labels before the start of cleaning.

6.1.7.3 Production Cleaner should refer to the cleaning schedule posted in accessible areas for use of the appropriate disinfectant as per rotation.

6.1.7.4 To ensure water ports and transfer equipment are not incidentally contaminated, care should be taken when collecting WFI or Purified Water for cleaning.

A. If a hose or pipe is needed to transfer water, ensure it is securely connected to the water port without leaks. Do not touch the water port directly with bare hands as this may contaminate the water port.
B. Before collecting or using water for cleaning, direct the hose to a drain and flush for NLT 1 minute.
C. Collect water or use for cleaning, then close the water port valve tightly to avoid leaks.

D. Remove the water hose and place it in a designated area to air dry. Ensure the hose is placed in a position that will drain any residual water.

6.1.7.5 Prepare disinfectants as per SOP IGN-027. Document the amount of disinfectant used in the appropriate Preparation of Disinfectant Dilutions Logbook.

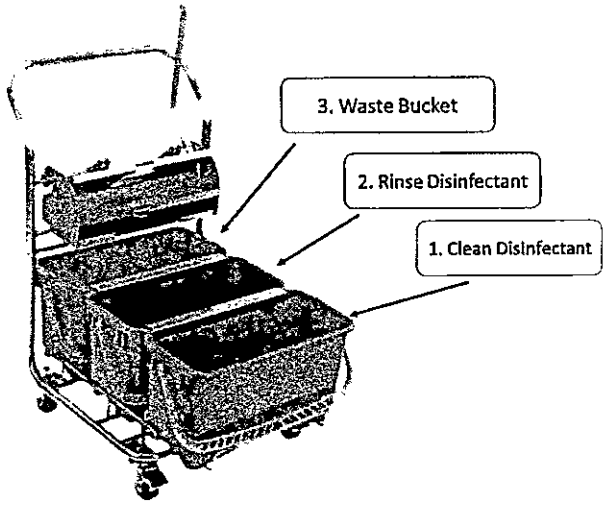
6.1.7.6 Production Cleaner should refer to the approved Facility Based Cleaning Flows for Cleanrooms as a guide to which rooms should be cleaned for Daily and Weekly cleaning, as well as provide direction where cleaning should begin and end.

**NOTE: Cleaning Flows are only a recommendation. When a specific room cannot be cleaned per the approved flow, due to unavoidable circumstances, cleaning can proceed in the following available room, as needed.**

6.1.7.7 The "Three Bucket System" works as follows: first bucket contains a clean disinfectant (or WFI/PW as applicable), second bucket contains a rinse disinfectant and is used to rinse the cleaning agent (or WFI/PW as applicable) from dirty mop, and third bucket is a waste bucket used to wring the mop. See Figure 2.

6.1.7.8 The flow for the "Three Bucket System" is as follows: dip mop into clean disinfectant, then wring mop into waste bucket to remove excess liquid and begin mopping. After mopping, insert mop into rinse bucket to remove dirty liquid, then wring mop to remove excess liquid. Repeat process until cleaning is finished.

**Figure 2: Three Bucket System**




6.1.7.9 Cleaning should be performed from the highest surface point to the lowest surface point (i.e., walls, equipment, and then floors, in sequential order), as well as, from the furthest surface point to the closest surface point (i.e., farthest corner of the room towards the exit that will be used to leave the room).

6.1.7.10 Cleaning should be performed uniformly in single overlapping strokes, ensuring all areas are reached by the mop without going over a single area multiple times.

6.2 Product Based Cleaning:

6.2.1 Product Based Cleaning is applicable to Process Equipment and Processing Rooms to avoid cross contamination majorly. It is separated as Minor Cleaning and Major Cleaning, and they are performed between batches.

**NOTE: Whenever cleaning a processing room along with multiple equipment located in the same room, open each related logbook (i.e., equipment and room) and document the type of cleaning (i.e., major cleaning / minor cleaning) under the "Description" column. Whenever the cleaning of each specific equipment is initiated, log such information in the respective logbook using only the "Start Date" and "Start Time" columns. Additionally, whenever the cleaning of each equipment is completed, document such information in the respective logbook using only the "Finish Date" and "Finish Time". Finally, the room should be cleaned last and the corresponding entries in the logbook related to the initiation and completion of the cleaning process need to be documented accordingly whenever the operation is started and completed. In case of cleanroom supporting areas, enter cleaning details in one single logbook.**

6.2.2 Before starting minor or major cleaning, put a check mark against the appropriate box on status label of the room, as applicable.

6.2.3 Minor Cleaning:

6.2.3.1 Minor cleaning is performed between batches of the same product type.

6.2.3.2 Ensure all evidence of the previous batch, including the batch record, all containers produced, and all raw materials, is cleared from the room. Ensure debris is removed off floor, and trash is removed from room.

6.2.3.3 Equipment should be cleaned per respective equipment cleaning SOP.

6.2.3.4 Using sterile 70% IPA, wipe down scales, tables, carts, windows, and doors.

6.2.3.5 Mop the floors using a mop wetted in WFI/PW following the "Three Bucket System" method and allow to dry.

6.2.3.6 After cleaning, sign the Cleaning, Use, and Maintenance Logbook for minor cleaning. Call the supervisor or designee to verify the cleaning.

6.2.3.7 Place a "CLEAN" label on the door with cleaning details.

6.2.3.8 Discard leftover cleaning agents through the drains in the Component Preparation Room, or designated areas. Clean buckets thoroughly with Purified Water after use.

6.2.4 Major Cleaning:

6.2.4.1 Major cleaning is performed between batches of different product type.

6.2.4.2 Ensure all evidence of the previous batch, including the batch record, all containers produced, and all raw materials, is cleared from the room. Ensure debris is removed off floor and trash is removed from room.

6.2.4.3 Cover room temperature / relative humidity monitoring probe in polyethylene bag to avoid water spill and physical damage to probe.

6.2.4.4 Equipment should be cleaned per respective equipment cleaning SOP.

**NOTE: Never spray WFI/PW directly on opening of exhaust duct, inlet supply grills, electrical fixtures, and light fixtures.**

6.2.4.5 Clean ceilings using a mop wetted in WFI/PW following the "Three Bucket System" method.

6.2.4.6 Clean walls and floors, using a mop wetted in WFI/PW following the "Three Bucket System" method and allow to dry.

6.2.4.7 Using sterile 70% IPA, wipe down scales, tables, carts, windows, and doors.

**NOTE: While performing the cleaning of the processing rooms, ensure the personnel and material flow are done in a way that avoids any cross contamination (i.e., do not enter the cleaned rooms while cleaning an un-cleaned room).**

6.2.4.8 After cleaning, sign the Cleaning, Use, and Maintenance Logbook for major cleaning and call the Supervisor or designee to verify the cleaning.

6.2.4.9 Place a "CLEAN" label on the door with cleaning details.

6.2.4.10 Discard leftover cleaning agents through the drains in the Component Preparation Room. Or designated areas. Clean buckets thoroughly with Purified Water after use.

6.2.5 Product Based cleaning for **Inspection and Packaging Rooms and Labeling and Packaging Room are** different as they are outside the cleanroom area but there is not open product exposed:

6.2.5.1 Minor cleaning is performed between batches of the same product type as below:

A. Ensure all evidence of the previous batch, including the batch record, all containers produced, and all raw materials, is cleared from the room. Ensure debris is removed off floor and trash is removed from room.

B. Equipment should be cleaned per respective equipment cleaning SOP.

C. Using sterile 70% IPA, wipe down scales, tables, carts, windows, and doors. If any debris or spills are present, mop floor using a mop wetted in WFI/PW.

D. After cleaning, sign the Cleaning, Use, and Maintenance Logbook for minor cleaning. Call the supervisor or designee to verify the cleaning.

E. Place a "CLEAN" label on the door with cleaning details.

F. Discard leftover cleaning agents through the drains in the Utilities Area, or designated areas. Clean buckets thoroughly with Purified Water after use.

6.2.5.2 Major cleaning is performed between batches of different product as below:

A. Ensure all evidence of the previous batch, including the batch record, all containers produced, and all raw materials, is cleared from the room. Ensure debris is removed off floor and trash is removed from room.

B. Equipment should be cleaned per respective equipment cleaning SOP.

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C. Using sterile 70% IPA, wipe down scales, tables, carts, windows, and doors.
D. Clean floors, using a mop wetted in WFI/PW and allow to dry.
E. After cleaning, sign the Cleaning, Use, and Maintenance Logbook for major cleaning. Call the supervisor or designee to verify the cleaning.
F. Place a "CLEAN" label on the door with cleaning details.
G. Discard leftover cleaning agents through the drains in the Utilities Area, or designated areas. Clean buckets thoroughly with Purified Water after use.

6.3 Facility Based Cleaning:

6.3.1 Facility Based Cleaning is applicable to Processing Areas only when production is inactive. If Production is active, cleaning may be performed in rooms that are not in use and areas that are in use must been cleaned whenever the activity is done. When production is active, refer to Product Based Cleaning as per section 6.2.

**NOTE: Production cleaner should not enter a room with cleaning utensils where production process is occurring.**

6.3.2 The different types of cleanings are detailed in Table 2. Types of Cleanings are defined by the frequency of the specific procedure required.

**Table 2: Types of Cleanings**

| Type of Cleaning | Identification | Main Surfaces | When Required |
|---|---|---|---|
| Daily | D | Floors | Every scheduled working day with Decon-Phene or Decon-Quat |
| Weekly | W | Ceilings, Walls, and Floors | Every Friday, or next working day if it is a holiday/not scheduled with Decon-Phene, Decon-Quat, or Decon-Spore |

**NOTE: Cleaning types should not overlap (i,e. Daily cleaning and Weekly cleaning should not be performed on the same day).**

6.3.3 Daily Cleaning is performed only in Non-Processing Areas and Cleanroom Support Areas (Refer to Table 1) using a disinfectant. Daily Cleaning is not performed in Processing Areas.

6.3.4 Weekly cleaning is performed in Processing Areas, Non-Processing Areas, and Cleanroom Support Areas, using disinfectants and sporicidal agents to reduce microbial bioburden majorly.

6.3.5 Weekly Cleaning supersedes Product Based Major cleaning and can be documented as equals when releasing a room for production.

6.3.6 Disinfectant Type use is determined by the disinfectant rotation as per SOP IGN-027 and approved rotation schedule posted in accessible areas. Table 3 shows an example of four-week period of Disinfectant Rotation.

**Table 3: Example of Disinfectant Rotation**

| M | T | W | T | F |
|---|---|---|---|---|
| Decon-Phene Daily Cleaning | Decon-Phene Daily Cleaning | Decon-Phene Daily Cleaning | Decon-Phene Daily Cleaning | Decon-Phene Weekly Cleaning |
| M | T | W | T | F |
| Decon-Phene Daily Cleaning | Decon-Phene Daily Cleaning | Decon-Phene Daily Cleaning | Decon-Phene Daily Cleaning | Decon-Spore Weekly Cleaning |
| M | T | W | T | F |
| Decon-Quat Daily Cleaning | Decon-Quat Daily Cleaning | Decon-Quat Daily Cleaning | Decon-Quat Daily Cleaning | Decon-Quat Weekly Cleaning |

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| M | T | W | T | F |
|---|---|---|---|---|
| Decon-Quat Daily Cleaning | Decon-Quat Daily Cleaning | Decon-Quat Daily Cleaning | Decon-Quat Daily Cleaning | Decon-Spore Weekly Cleaning |

6.3.7 Non-Processing Areas, Cleanroom Support Areas, and Processing Areas are cleaned as per the schedule in Table 4.

**Table 4: Non-Processing Areas, Cleanroom Support Areas, and Processing Areas Routine Schedule**

| Cleaning Agents | Sterile 70% IPA | Decon-Phene or Decon-Quat | Decon-Spore | WFI |
|---|---|---|---|---|
| **Surfaces** | **Windows, Handles, Doors** | **Floors** | | **Ceilings** |
| **Non-Processing Areas** | | | | |
| Non-Cleanroom Corridors | D, W | D, W | W | N/A |
| Change Rooms / Lockers | D, W | D, W | W | N/A |
| Microbiology Laboratory | D, W | D, W | W | N/A |
| MLT Laboratory | D, W | D, W | W | N/A |
| Quality Control Laboratory | D, W | D, W | W | N/A |
| Vestibule | D, W | D, W | W | N/A |
| Restrooms | D, W | D, W | W | N/A |
| R & D Laboratory | W | W | W | N/A |
| Warehouses (Shipping and Receiving) | W | W | W | N/A |
| Inspection and Packaging | W | W | W | N/A |
| Labeling and Packaging | W | W | W | N/A |
| Tech Space | N/A | W | W | N/A |
| Utility Area / Boiler Room | N/A | W | W | N/A |
| **Surfaces** | **Windows, Handles, Doors** | **Walls and Floors** | | **Ceilings** |
| **Cleanroom Support Areas** | | | | |
| Cleanroom Corridors | D, W | D, W | W | W |
| Personnel Gowning and De-Gowning Rooms | D, W | D, W | W | W |
| Material Airlocks | D, W | D, W | W | W |
| Component Preparation Room | D, W | D, W | W | W |
| Clean Equipment Room | D, W | D, W | W | W |
| Cleaning Supplies Room | D, W | D, W | W | W |
| **Processing Areas** | | | | |
| Filling Rooms | W | W | W | W |
| Formulation Rooms | W | W | W | W |
| Autoclave Load | W | W | W | W |
| Autoclave Unload | W | W | W | W |
| Samples Rooms | W | W | W | W |
| Sterility Room | W | W | W | W |
| Tank WIP Room | W | W | W | W |

**NOTE: Certain rooms may have different cleaning frequencies than what is stated in Steps 6.3.8 and 6.3.9. Always follow what is specified in Table 4 as a default.**

6.3.8 Daily Cleaning:

6.3.8.1 Daily cleaning is performed every scheduled working day in Non-Processing Areas and Cleanroom Support Areas, with exceptions, as listed in Table 4.

6.3.8.2 Prior to cleaning, sweep away dust and debris, and dust-off surfaces as needed.

6.3.8.3 Prepare appropriate cleaning solution and document the amount of disinfectant used in the Preparation of Disinfectant Dilutions Logbook.

**NOTE: Cleanroom Cleaning should begin in the highest classified areas (i.e., filling rooms, formulations room) and should end in the least classified areas (i.e., corridor 301, anteroom), as possible. However, ensure personnel and material flow are in a way that avoids cross contamination (i.e., do not enter cleaned rooms from an un-cleaned room). Refer to approved Facility Based Cleaning Flows for Cleanrooms.**

6.3.8.4 Using sterile 70% IPA, wipe down windows, handles, and doors. Also wipe any chairs, tables, phones, racks, carts, etc., when applicable.

6.3.8.5 Mop the floors using a mop wetted in disinfectant solution (refer to EOL I-003 Miscellaneous List and refer to SOP IGN-027 for preparation of disinfectant solution), following the "Three Bucket System" method, or other bucket system when applicable, and allow a minimum contact time of 10 minutes. Once contact time has been allowed, confirm the action within the Cleaning, Use, and Maintenance Logbook.

6.3.8.6 Mop the floors using a mop wetted in WFI following the "Three Bucket System" method, or other bucket system when applicable, to remove disinfectant residues and allow to dry.

6.3.8.7 After cleaning, sign the Cleaning, Use, and Maintenance Logbook for daily cleaning and call the Supervisor or designee to verify the cleaning.

6.3.8.8 Discard leftover cleaning agents through the drains in the Component Preparation Room, or designated areas. Clean buckets thoroughly with Purified Water after use.

6.3.9 Weekly Cleaning:

6.3.9.1 Weekly cleaning is performed every Friday (or previous/next working day, as necessary) in Non-Processing Areas, Cleanroom Support Areas and Processing Areas, with exceptions, as listed in Table 4 (if Friday is in production, clean upon completion or next working day). In addition to the daily cleaning procedure performed as per section 6.3.8, ceilings and walls are included as part of weekly cleaning.

**NOTE: If management is aware the Weekly cleaning cannot be completed for all rooms on Friday, cleaning may be performed Thursday and Friday. If cleaning is started on Friday but cannot be completed, cleaning may be continued on Monday followed by routine schedule starting on Tuesday or the next working day, as required.**

6.3.9.2 Prior to cleaning, sweep away dust and debris, and dust-off surfaces as needed.

6.3.9.3 Prepare appropriate cleaning solution and document the amount of disinfectant used in the Preparation of Disinfectant Dilutions Logbook.

**NOTE: Cleanroom Cleaning should begin in the highest classified areas (i.e., filling rooms, formulations room) and should end in the least classified areas (i.e., corridor 301, anteroom), as possible. However, ensure personnel and material flow are in a way that avoids cross contamination (i.e., do not enter cleaned rooms from an un-cleaned room). Refer to approved Facility Based Cleaning Flows for Cleanrooms.**

6.3.9.4 Clean ceilings using a mop wetted in WFI following the "Three Bucket System" method.

6.3.9.5 Clean the walls using a mop wetted in disinfectant solution (refer to EOL I-003 Miscellaneous List and refer to SOP IGN-027 for preparation of disinfectant solution), following the "Three Bucket System" method, or other bucket system when applicable, and allow a minimum contact time of 10 minutes.

6.3.9.6 Mop walls using a mop wetted in WFI following the "Three Bucket System" method, or other bucket system when applicable, to remove disinfectant residues and allow to dry.

6.3.9.7 Using sterile 70% IPA, wipe down windows, handles, and doors. Also wipe any chairs, tables, phones, racks, carts, etc., when applicable.

6.3.9.8 Mop the floors using a mop wetted in disinfectant solution (refer to EOL I-003 Miscellaneous List and refer to SOP IGN-027 for preparation of disinfectant solution), following the "Three Bucket System" method, or other bucket system when applicable, and allow a minimum contact time of 10 minutes. Once contact time has been allowed, confirm the action within the Cleaning, Use, and Maintenance Logbook.

6.3.9.9 If any Pass box present in room, clean as per section 6.5.

6.3.9.10 Mop the floors using a mop wetted in WFI following the "Three Bucket System" method, or other bucket system when applicable, to remove disinfectant residues and allow to dry.

6.3.9.11 After cleaning, sign the Cleaning, Use, and Maintenance Logbook for weekly cleaning and call the Supervisor or designee to verify the cleaning.

6.3.9.12 Place "CLEAN" label on the door if cleaning in a Processing Area. Do not place labels in Non-Processing Areas and Cleanroom Support Areas.

**NOTE: Label Inspection and Packaging Room and Labeling & Packaging Room after all cleanings.**

6.3.9.13 Discard leftover cleaning agents through the drains in the Component Preparation Room. Clean buckets thoroughly with Purified Water after use.

6.4 Return all cleaning products, mops, and pails to the cleaning supplies area after cleaning and sanitizing.

6.4.1 Clean buckets and pails thoroughly inside and out until no visible residue is observed, using Purified Water in the Component Preparation Room, or designated areas. Invert items to allow removal of excess water and wipe with a lint free cloth.

6.4.2 Mop heads should be discarded daily. Discard and replace mop head if it becomes visibly dirty at any point.

6.4.3 Wipe "Three Bucket System" cart with sterile 70% IPA prior to replacing buckets on it.

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6.5 Cleaning of Production Passbox:

6.5.1 If any room within Production contains a Pass box for material transfer between two classified rooms or between a classified room and an unclassified room, cleaning for this Pass box is required to be performed on a Weekly Basis.

6.5.1.1 Prior to cleaning, dust-off surfaces as needed.

6.5.1.2 Wipe down interior and exterior surfaces from top to bottom using sterile 70% IPA and a lint free cloth.

## 7.0 REVISION HISTORY

| Revision No. | Effective Date | Description of Changes |
|---|---|---|
| 01 | AUG 29 2018 | Original SOP |
| 02 | FEB 12 2019 | 1. Include Room numbers in Table 1 for further description<br>2. Remove 6.1.8 and 6.1.9 as 6.1.10 covers the same information to advise user that different areas have different supplies that should not be mixed and should be labeled appropriately to prevent that<br>3. Edit sections 6.2.3.7, 6.2.4.10, 6.3.6.7, and 6.3.7.10 to update the location of where buckets are cleaned as utensils for processing areas should not be taken to non-processing areas.<br>4. Include disinfectant types in Table 2<br>5. Edit Tables 3 and 4 for clarification that walls and floors use disinfectant and processing areas should include windows, handles, and doors<br>6. Note included under section 6.3.7 to address the procedure if weekly cleaning cannot be completed solely on Friday<br>7. Update section 6.4.1 and 6.4.3 to include the cleaning of buckets in wash room as utensils for processing areas should not be taken to non-processing areas and wipe Three Bucket system cart with 70% IPA<br>8. Rearrange steps 6.2.4.3 and 6.3.7.3 so that ceilings and walls are cleaned prior to wiping windows with IPA as water streaks from walls may fall on the windows<br>9. Include section 6.1.10 and 6.1.11 to mention cleaning schedule that will be posted and documenting disinfectant dilution in appropriate logbook.<br>10. Include wiping of carts, rack, phones, and other items inside rooms, when applicable in sections 6.3.6.3 and 6.3.7.6. |
| 03 | SEP 23 2019 | 1. Table 1 updated to ensure all missing rooms are included.<br>2. Clarify types of areas in step 6.1.5.<br>3. Figure 1 updated to better explain room cleaning flow.<br>4. Step 6.1.7 included for general cleaning strategies.<br>5. Include Step 6.2.5 to detail cleaning for Visual Inspection and Labeling/Packaging Room as they are outside cleanroom but still used for process.<br>6. Clarify step 6.3.1 to clarify cleaning may be performed in unused rooms when production is active.<br>7. Include Step 6.3.5 to specify the Weekly Cleaning supersedes Major cleaning.<br>8. Table 2 was updated to remove Bi-weekly cleaning as a type of cleaning since it is the same as Weekly procedure wise. Disinfectant rotation is the only difference which is explained in step 6.3.2. Bi-weekly cleaning removed from entire SOP.<br>9. Note under Table 2 added to clarify that Daily cleaning and Weekly cleaning procedures should not occur on the same day.<br>10. Table 3 was added to show example of disinfectant rotation.<br>11. Table 4 updated to include missing rooms and update cleaning frequencies for all rooms. Previous table 3 and 4 were combined to form Table 4. |
| 04 | DEC 02 2020 | 1. Include instruction in steps 6.3.8.5 and 6.3.9.5 about confirming contact time in Cleaning, Use, and Maintenance Logbook. |
| 05 | MAR 09 2021 | 1. Include Step 6.1.7.5 and Note under it to include use of Facility Based Cleaning Flows for Cleanrooms.<br>2. Revise Notes under steps 6.3.8.3 and 6.3.9.3 to ensure cleaning personnel is aware of flow of cleaning, and also referring to the new approved cleaning flows which will further explain the proper flow. |

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| Revision No. | Effective Date | Description of Changes |
|---|---|---|
| 06 | AUG 23 2022 | 1. Include procedure for cleaning of a Passbox.<br>2. Update weekly cleaning procedure to reflect proper flow and include Passbox cleaning, when applicable. |
| 07 | SEP 08 2022 | 1. Included Step 6.1.7.4 for collection/use of WFI or Purified Water for cleaning.<br>2. Removed the mention of R&D Labs 406 and 407 following facility modifications.<br>3. Updated the wording of Visual Inspection Room to Inspection and Packaging Rooms. |
| 08 | JAN 2 7 2023 | 1. Note under Step 6.2.1 is extended to explain the cleaning activities for Clean Room Supporting areas. |

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 555 Winderley Place, Suite 200<br>Maitland, FL 32751<br>(407)475-4700 Fax:(407)475-4768<br>ORAPHARM2_RESPONSES@fda.hhs.gov | 4/19/2021-4/30/2021*<br>FEI NUMBER<br>3015156709 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jugal K. Taneja, Managing Member

| FIRM NAME | STREET ADDRESS |
|---|---|
| BPI Labs LLC | 12393 Belcher Rd S Ste 450 |
| CITY, STATE, ZIP CODE, COUNTRY<br>Largo, FL 33773-3097 | TYPE ESTABLISHMENT INSPECTED<br>Sterile Drug Manufacturer and 503B Outsourcing Facility |

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:**
Pre-Approval, NDA #205029 Supplement 10: Epinephrine, USP Pre-Filled Syringes 1mg/mL

## OBSERVATION 1

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically, during inspection, it was observed that the equipment "Groinger Plunger Rod and Labelling Machine type SMKE with de-nester" intended for labeling the pre-filled epinephrine syringes referenced in your NDA application has not been installed and qualified for use.

## OBSERVATION 2

Potential suppliers were not evaluated and selected based on their ability to meet specified requirements.

Specifically, your firm was not evaluating suppliers based upon their ability to meet requirements established in your *Vendor Management System* procedure (SOP IGN-034) and *Purchasing System* procedure (SOP IPC-001). Your firm's initial qualification (signed 02/26/2019) of your supplier of sterile 1 mL syringes indicates that a "review of collected data shows that the company has a vigorous quality system and capable of meeting customer expectations," but the approved supplier did not provide the information required per your firm's procedures and the questionnaire provided. For example, the initial *Questionnaire for Customers* provided by your supplier as a self-audit indicated that their Site Master File, manufacturing equipment, site maps and

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Saundrea A Munroe, Investigator<br>Emma R Schaefer, Investigator<br>Jessica L Pressley, Investigator | X Saundrea A Munroe Investigator Signed By: Saundrea A. Munroe - S Date Signed: 04-30-2021 10:43:20 4/30/21 | 4/30/2021 |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 555 Winderley Place, Suite 200<br>Maitland, FL 32751<br>(407)475-4700 Fax:(407)475-4768<br>ORAPHARM2_RESPONSES@fda.hhs.gov | 4/19/2021-4/30/2021*<br>FEI NUMBER<br>3015156709 |

| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | |
|---|---|
| Jugal K. Taneja, Managing Member | |
| FIRM NAME<br>BPI Labs LLC | STREET ADDRESS<br>12393 Belcher Rd S Ste 450 |
| CITY, STATE, ZIP CODE, COUNTRY<br>Largo, FL 33773-3097 | TYPE ESTABLISHMENT INSPECTED<br>Sterile Drug Manufacturer and 503B Outsourcing Facility |

drawings, an explanation of how product is protected from the manufacturing environment, deviation handling procedures, previous deviations and OOS syringes, and an explanation of rejected batches of syringes within the last year were not provided. The supplier indicated that this information could be provided at the next on-site audit. There has not been an on-site audit conducted since this initial qualification nor is one scheduled by the firm. Additionally, this self-assessment indicated that the supplier has not been inspected by a regulating body and doesn't confirm the supplier's understanding of FDA's regulations, which is a requirement of the firm's *Purchasing System* procedure.

## OBSERVATION 3

Risk analysis is inadequate.

Specifically, your firm's risk analysis conducted as part of the *Combination Product Compliance 21 CFR Part 4 Drug and Device Constituent Parts* document you identified as the design history file for your firm's 1 mL epinephrine syringe does not adequately identify the hazards, estimated risks, and mitigations associated with the use of your finished combination product.

For example, your firm identifies the glass syringe and rubber plunger components of your finished 1 mL epinephrine syringe as high risk for particulate matter, bacterial endotoxin, and lack of sterility in the *Product Development Report for Epinephrine Injection, USP 1 mG/mL* under section 2.1.3. In your firm's design history file your risk analysis conducted for the finished 1 mL epinephrine syringe device does not evaluate the risk levels for the eight risks identified by your firm. Additionally, one of the mitigations listed for risk of particulates is "incoming materials controls". Your firm's supplier control's do not adequately evaluate your supplier's capabilities of meeting the supplier requirements established by your firm, including technical and regulatory requirements. Your firm's supplier of syringes for this combination product was not subject to a quality

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE<br>Saundrea A Munroe, Investigator<br>Emma R Schaefer, Investigator<br>Jessica L Pressley, Investigator | X Saundrea A Munroe Investigator Signed By: Saundrea A. Munroe Date Signed: 04-30-2021 10:43:20 4/30/21 | DATE ISSUED<br>4/30/2021 |
|---|---|---|---|

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 555 Winderley Place, Suite 200<br>Maitland, FL 32751<br>(407)475-4700 Fax:(407)475-4768<br>ORAPHARM2_RESPONSES@fda.hhs.gov | 4/19/2021-4/30/2021*<br>FEI NUMBER<br>3015156709 |

| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | |
|---|---|
| Jugal K. Taneja, Managing Member | |
| FIRM NAME<br>BPI Labs LLC | STREET ADDRESS<br>12393 Belcher Rd S Ste 450 |
| CITY, STATE, ZIP CODE, COUNTRY<br>Largo, FL 33773-3097 | TYPE ESTABLISHMENT INSPECTED<br>Sterile Drug Manufacturer and 503B Outsourcing Facility |

agreement and did not provide evidence to support their abilities to meet your firm's established supplier requirements during their initial self-audit approved on 02/26/2019.

## OBSERVATION 4

Procedures for design transfer have not been adequately established.

Specifically, your firm's design history file for your 1 mL epinephrine syringe combination product did not contain a documented design transfer that supported the device's design was correctly translated into production specifications. Under design transfer your firm documented "there is no transfer involved."

## OBSERVATION 5

The type and extent of control to be exercised over the product and suppliers was not clearly defined.

Specifically, your firm did not establish a quality agreement with your supplier that defined the type and extent of control to be exercised over the sterile 1 mL syringe that is a component of your firm's sterile 1 mL epinephrine syringe combination product until 04/22/2021. This is required per SOP IGN-034 Section 6.3.6 upon vendor approval. Your firm's supplier of sterile 1 mL syringes was approved on 02/26/2019.

## *DATES OF INSPECTION

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Saundrea A Munroe, Investigator<br>Emma R Schaefer, Investigator<br>Jessica L Pressley, Investigator<br>X Saundrea A Munroe Investigator Signed By: Saundrea A. Munroe - S Date Signed: 04-30-2021 10:43:20 | 4/30/2021 |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 555 Winderley Place, Suite 200<br>Maitland, FL 32751<br>(407)475-4700 Fax:(407)475-4768<br>ORAPHARM2_RESPONSES@fda.hhs.gov | 4/19/2021-4/30/2021*<br>FEI NUMBER<br>3015156709 |

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| Jugal K. Taneja, Managing Member | |
| FIRM NAME<br>BPI Labs LLC | STREET ADDRESS<br>12393 Belcher Rd S Ste 450 |
| CITY, STATE, ZIP CODE, COUNTRY<br>Largo, FL 33773-3097 | TYPE ESTABLISHMENT INSPECTED<br>Sterile Drug Manufacturer and 503B Outsourcing Facility |

4/19/2021(Mon), 4/20/2021(Tue), 4/21/2021(Wed), 4/22/2021(Thu), 4/23/2021(Fri), 4/26/2021(Mon), 4/27/2021(Tue), 4/28/2021(Wed), 4/30/2021(Fri)

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
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| | Saundrea A Munroe, Investigator<br>Emma R Schaefer, Investigator<br>Jessica L Pressley, Investigator | X Saundrea A Munroe Investigator Signed By: Saundrea A. Munroe - S Date Signed: 04-30-2021 10:43:20 | 4/30/2021 |

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| Jugal K. Taneja, Managing Member | |
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| CITY, STATE, ZIP CODE, COUNTRY<br>Largo, FL 33773-3097 | TYPE ESTABLISHMENT INSPECTED<br>Sterile Drug Manufacturer and 503B Outsourcing Facility |

## Annotations to Observations

Observation 1: Not annotated

Observation 2: Not annotated

Observation 3: Not annotated

Observation 4: Not annotated

Observation 5: Not annotated

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Saundrea A Munroe, Investigator<br>Emma R Schaefer, Investigator<br>Jessica L Pressley, Investigator | X 4/30/21<br>Saundrea A Munroe<br>Investigator<br>Signed By: Saundrea A. Munroe - S<br>Date Signed: 04-30-2021 10:43:20 | 4/30/2021 |

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

bpi Labs

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May 21, 2021

Monica R. Maxwell
Program Division Director
Office of Pharmaceutical Quality Operations (OPQO), Division II
Food and Drug Administration
ORAPharm2_responses@fda.hhs.gov

**Subject: Response to FDA Inspectional Observations from 04/19/2021 to 04/30/2021**

Dear Madam,

This correspondence is in response to the 04/19/2021 through 04/30/2021 pre-approval inspection of NDA # 205029 Supplement # 9: Epinephrine Injection, USP 10 mg / 10 mL (10 mL Vial) and NDA # 205029 Supplement # 10: Epinephrine Injection, USP 1 mg / mL (1 mL Syringe) to be manufactured commercially by BPI Labs, LLC, at 12393 Belcher Road, Suite # 450, Largo, FL 33773 (FEI Number 3015156709), upon FDA approval.

This communication is in response to the Form FDA 483 Inspectional Observations issued to BPI Labs, LLC ("BPI") specific to its NDA # 205029 Supplement # 10: Epinephrine Injection, USP 1 mg / mL (1 mL Syringe) by FDA Investigators Ms. Saundrea A Munroe and Ms. Emma R Schaefer (collectively, referred to as the "Investigators").

BPI would like to bring to your attention that no FDA 483 observations were issued to NDA # 205029 Supplement # 9: Epinephrine Injection, USP 10 mg / 10 mL (10 mL Vial) at the end of the inspection. Investigators mentioned during the close out meeting that this drug product was going to be recommended for approval. BPI respectfully requests FDA to facilitate the approval of the NDA # 205029 Supplement # 9: Epinephrine Injection, USP 10 mg / 10 mL (10 mL Vial) in order to commence the commercial manufacturing as soon as possible.

In addition, BPI would like to acknowledge that no FDA 483 observations were issued during the 503B outsourcing facility inspection that occurred simultaneously with the pre-approval inspection. The 503B outsourcing facility inspection was conducted by FDA Investigator Ms. Jessica L Pressley.

In regard to the Form FDA 483 Inspectional Observations issued to BPI specifically to its NDA # 205029 Supplement # 10: Epinephrine Injection, USP 1 mg / mL (1 mL Syringe), BPI accepts the Investigators' observations and commits to address the issue expeditiously. BPI believes it has taken and commits to continue to take any and all necessary measures to ensure its customers

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well-being and safety. Enclosed please find an attachment that addresses BPI's responses to the FDA Investigators' observations on an individual and systemic basis.

Our corrective action plan will address all issues effectively and comply with Current Good Manufacturing Practices (cGMP) Regulations (Title 21, Code of Federal Regulations, Parts 210, 211, and 4).

BPI would like to inform the Agency that all corrective actions taken have been completed, as can be evidenced from our responses enclosed with this letter, except Observation 1.

BPI expects to complete the qualification of the intended equipment, TechLine Horizontal Roller Syringe Wrap Labeling System Machine, to be used in commercial labeling of NDA # 205029 Supplement # 10: Epinephrine Injection, USP 1 mg / mL (1 mL Syringe) and submit the executed qualification protocols and associated final report to FDA on or before 09/30/2021.

BPI's action plan for Observation 1 includes the specifics of its actions along with targeted timelines. We will closely monitor the implementation of the plan and will provide your Office with updates along with evidence of implementation. Should we change any of our commitments, we will provide you with our reasons and supporting documentation.

Henceforth, upon receipt of BPI's final response related to this FDA 483 observation, BPI respectively requests that the Agency accepts the submitted executed qualification documentation of the TechLine Horizontal Roller Syringe Wrap Labeling System Machine in lieu of a second separate visit to our facility to inspect the qualification exercise of the mentioned machine onsite. Instead, the Agency would be more than welcome to inspect such documentation at our facility at any convenient time, i.e., next BPI cGMP inspection or pre-approval inspection associated with BPI other filed NDAs or ANDAs.

Accordingly, we would like to request a review of our response and action plan at your earliest convenience.

Finally, as per Investigators' request during the close out meeting, BPI is also enclosing along with this response the information related to non-conformance NCR No. I-21004 associated to the sanitization of the Purified Water System.

Please feel free to contact me at (727) 471 0850 Extension 200 if you have any questions or concerns with our responses.

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Cordially,

M. Salazar

Mauricio Salazar
Chief Quality & Compliance Officer
BPI Labs, LLC
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**PRE-APPROVAL, NDA # 205029 SUPPLEMENT 10: EPINEPHRINE, USP PRE-FILLED SYRINGES 1 MG/ML**

**OBSERVATION 1:**

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically, during inspection, it was observed that the equipment "Groinger Plunger Rod and Labelling Machine type SMKE with de-nester" intended for labeling the pre-filled epinephrine syringes referenced in your NDA application has not been installed and qualified for use.

**BPI'S RESPONSE TO OBSERVATION 1:**

BPI acknowledges and accepts the investigator's observation.

BPI's application NDA # 205029 Supplement 10 for Epinephrine, USP Pre-Filled Syringes 1 mg/mL submitted to FDA on 03/19/21 included the current installed and qualified labeling machine, i.e., Labeler (Model #: Q105 Stepper), referenced via SOP IPK-004 "Handling of the Labeler (Model # Q105 Stepper)", as part of the proposed intended commercial Labeling Master No.: PK-I117-0-10 "Master Batch Packaging Record – Labeling Instructions" document for this product (refer to Exhibit – 1.1).

In regards to the observation noted by the FDA, BPI would like to clarify the situation encountered with the Q105 Stepper labeling machine, included in the Supplement information given to FDA as part of the submission, and the "Groinger Plunger Rod and Labelling Machine type SMKE with de-nester" (hereinafter referred to as "Groninger labeling machine") as discussed with the FDA investigators during this inspection.

BPI's initial intention was to utilize the Q105 Stepper labeling machine for the labeling of the pre-filled epinephrine syringes as it was expected to be suitable for both vials and syringes configurations. However, further technical and operational assessment of the Q105 Stepper labeling machine along with discussion with the equipment manufacturer revealed that this equipment will not be the most ideal labeling machine to be used for the pre-filled syringes. This finding identified the need to re-evaluate the need to purchase and commission the Groninger labeling machine for the labeling operation of the pre-filled epinephrine syringes.

At this time, the available quotation received by BPI for this Groninger labeling machine was shown to the FDA investigators (refer to Exhibit – 1.2) and also the explanation of the technical constraints related to the current installed and qualified Q105 Stepper labeling machine for the

pre-filled syringes was presented during the inspection. BPI confirmed that the Groninger labeling machine had not been purchased, installed, and qualified for use.

After the FDA inspection, BPI contacted the manufacturer of the Groninger labeling machine to inquire about its availability based on the past quotation. Unfortunately, the manufacturer confirmed that due to the COVID-19 pandemic this equipment has very long lead time for delivery.

As a result, BPI searched for alternate suitable labeling machines for the labeling operation of pre-filled syringes. BPI identified the TechLine Horizontal Roller Syringe Wrap Labeling System machine, manufactured by Quadrel Labeling Systems, as adequate for the intended use based on the technical specifications and product design (refer to Exhibit – 1.3 for the quotation provided by this firm).

Quadrel Labeling Systems confirmed that the TechLine labeling machine is expected to be delivered to BPI on or before 08/31/21 (refer to Exhibit – 1.4 for copy of purchase order).

BPI commits to install and qualify the TechLine labeling machine and expects to complete this activity and submit the executed qualification protocols and associated final report to the FDA on or before 09/30/21.

**OBSERVATION 2:**

Potential suppliers were not evaluated and selected based on their ability to meet specified requirements.

Specifically, your firm was not evaluating suppliers based upon their ability to meet requirements established in your *Vendor Management System* procedure (SOP IGN-034) and *Purchasing System* procedure (SOP IPC-001). Your firm's initial qualification (signed 02/26/2019) of your supplier of sterile 1 mL syringes indicates that a "review of collected data shows that the company has a vigorous quality system and capable of meeting customer expectations," but the approved supplier did not provide the information required per your firm's procedures and the questionnaire provided. For example, the initial *Questionnaire for Customers* provided by your supplier as a self-audit indicated that their Site Master File, manufacturing equipment, site maps and drawings, an explanation of how product is protected from the manufacturing environment, deviation handling procedures, previous deviations and OOS syringes, and an explanation of rejected batches of syringes within the last year were not provided. The supplier indicated that this information could be provided at the next on-site audit. There has not been an on-site audit conducted since the initial qualification nor is one scheduled by the firm. Additionally, this self-assessment indicated that the supplier has not been inspected by a regulatory body and doesn't confirm the supplier's understanding of FDA's regulations, which is a requirement of the firm's *Purchasing System* procedure.

**BPI'S RESPONSE TO OBSERVATION 2:**

BPI acknowledges and accepts the investigator's observation. However, BPI would like to explain to the Agency all the available procedures that were in place at the time of the FDA inspection to evaluate and select potential vendors based on their ability to meet specified requirements.

New vendors are initially approved in the quality system following the requirements documented in SOPs IPC-001 "Purchasing System" and IGN-034 "Vendor Management System." Then, vendors are re-qualified in a periodic manner as per the guidelines written in both mentioned procedures. Both the initial and re-qualification exercises are well defined to assess the adequacy of the vendor performance at all times.

Refer to Exhibit – 5.1 for copy of mentioned SOPs IPC-001 Revision No. 04 and IGN-034 Revision No. 04 that were effective at the time the FDA inspection was conducted.

In regards to the observation noted by the FDA, specifically related to SCHOTT Schweiz AG which is the vendor supplying the syringes for the epinephrine pre-filled syringes 1 mg/mL, BPI would like to clarify the execution of all available procedures that were in place at the time of the

FDA inspection to evaluate and select potential vendors based on their ability to meet specified requirements, consistent with the quality system standards available in both above mentioned SOPs.

Firstly, SCHOTT Schweiz AG was initially approved in the quality system on 02/26/19 (refer to Exhibit – 5.2). SCHOTT Schweiz AG is one of the world's leading manufacturers of special glass and polymers including vials, cartridges, and syringes ready to use for the pharmaceutical industry; this company was established in year 1930.

During the initial qualification of this reputed vendor, BPI requested a variety of technical documentation for the components that were required as part of product development as well as an understanding of the quality principles of this firm. Based on their internal administrative process, SCHOTT Schweiz AG does not complete feedback questionnaires and rather they provide their own self-assessment explaining several information about the company. As part of this initial process, BPI identified few points that were not fully communicated and explained in SCHOTT Schweiz AG's self-assessment and despite making diligent efforts by BPI to clarify such information as further preliminary understanding of the vendor, SCHOTT Schweiz AG did not provide the clarifications requested due to some organizational reason, out of BPI's control. That being said, as stated below BPI has been able to get further clarifications on these points.

Further evaluation of this firm made at the time of initial qualification revealed that a US DMF (i.e., 18416) was filed for the components SCHOTT Schweiz AG intended to distribute to United States. In addition, the technical documentation related to the components BPI was interested to acquire was found highly accurate and complete (refer to Exhibit – 2.1 for an example of technical data). Moreover, SCHOTT Schweiz AG presented certifications from accredited organizations in regards to ISO 9001 and ISO 15378 (refer to Exhibit – 2.2) confirming vendor's understanding in quality (i.e., development, engineering, manufacturing and sales of primary packaging materials made of glass tubing and polymers) and vendor's experience in audits under a regulatory environment. Finally, the vendor reputation verified during initial approval confirmed that SCHOTT Schweiz AG adheres to good quality standards according to available public data.

BPI approved SCHOTT Schweiz AG on 02/26/19 to supply components for research and development use because all data indicated that the vendor had a robust quality system capable of meeting customer expectations, inline with technical data, certifications, vendor history, and DMF filing in United States.

BPI would like to clarify to the Agency that SCHOTT Schweiz AG is a quality focused and highly knowledgeable firm. This company has provided detailed technical documents from day one related to the design, manufacturing, and controls for its components, confirming that this mentioned vendor fully understands the GMP regulations / expectations in an FDA environment.

Secondly, this vendor was re-qualified in the quality system on 02/17/21 (refer to Exhibit – 5.3), based on two years re-qualification period. As part of this re-qualification process, SCHOTT Schweiz AG performance was scrutinized based on technical data, available certifications in ISO 13485, ISO 14001, and ISO 45001 (refer to Exhibit – 2.3), and vendor history with BPI since the initial approval, and found out that six shipments were received, inspected, tested, and released for use at BPI without any problem or unwanted trend, corroborating one more time that this vendor had proper systems in place capable of meeting customer expectations and that BPI had available procedures to evaluate the quality of the components received.

In accordance with above specifics, please be advised that BPI has carefully evaluated SCHOTT Schweiz AG and has selected it based on its ability to meet specified requirements, which has been further substantiated with SCHOTT Schweiz AG's performance since February 2019 to date (i.e., no rejections, no unwanted trends).

It is important to inform to the Agency that all these explanations and evidences were shown and discussed with the FDA investigator during the inspection.

Nonetheless as part of this observation, BPI performed a thorough evaluation of all vendors related to commercial materials and components, and confirmed that adequate initial vendor approval and vendor re-qualification exercises have been systematically conducted including the periodic evaluation of vendor's performance and materials / components quality, inline with the requirements of SOPs IPC-001 and IGN-034. This finding further validates that BPI has been following its internal controls at all times.

As a further assurance, BPI contacted SCHOTT Schweiz AG again to inquire one more time about some information that was not provided by this vendor at the time of initial qualification. As a result SCHOTT has agreed to have a remote audit discussion with BPI with the purpose of clarifying all the pending items, including the ones pointed out by the Agency. During this process conducted on 05/20/21, SCHOTT Schweiz AG explained the majority of the open questions and shared specifics about their controls in place, validating that SCHOTT Schweiz AG has a strong quality system tailored to meet customer needs (refer to Exhibit – 2.4 for the updated SCHOTT Schweiz AG report).

As a further assurance and as part of continuous improvement, BPI revisited the wording of its controls for initial and re-qualification of vendors and identified an opportunity for enhancement to present in a more explicit manner the current expectations and practices on this topic. Consequently, BPI has revised SOP IGN-034 "Vendor Management System" in the quality system to clarify the requirements of initial and re-qualification of vendors, including the addition of handling self-assessments provided by the firms in lieu of BPI's feedback questionnaire. The revised SOP was made effective on 05/18/21 as Revision No. 05; all users of this SOP were part of the review and approval process (refer to Exhibit – 5.7 for a copy of the revised SOP along with the respective change control). BPI believes that clearer instructions on

this SOP would contribute to avoid misinterpretations about the process of evaluating, selecting, and monitoring vendors.

As a final point, BPI would like to clarify to the Agency that SCHOTT Schweiz AG is a vendor classified for research and development use only at this specific time (i.e., no components is currently used in any commercial product) and for this reason on-site audit need as per SOP IGN-034 has not been undertaken yet. Once this vendor is transitioned from research and development to commercial, at that time the requirement of on-site audit will be assessed as per the frequency established in this mentioned SOP, and if selected, this vendor will be added to the "Vendor On-site Audit Tentative Schedule Plan" for on-site audit planning and execution.

In conclusion, BPI believes that procedures that defined the evaluation and selection of vendors based on their ability to meet specified requirements were established in the quality system from day one and were executed effectively, that initial and re-qualification processes for SCHOTT Schweiz AG has been done methodically, and that SCHOTT Schweiz AG is a vendor considered in respectable standards and capable of meeting customer needs, reaffirming that BPI has followed its SOPs and has operational systems to control and monitor vendors in a consistent manner.

**OBSERVATION 3:**

Risk analysis is inadequate.

Specifically, your firm's risk analysis conducted as part of the *Combination Product Compliance 21 CFR Part 4 Drug and Device Constituent Parts* document you identified as the design history file for your firm's 1 mL epinephrine syringe does not adequately identify the hazards, estimated risks, and mitigations associated with the use of your finished combination product.

For example, your firm identifies the glass syringe and rubber plunger components of your finished 1 mL epinephrine syringe as high risk for particulate matter, bacterial endotoxin, and lack of sterility in the *Product Development Report for Epinephrine Injection, USP 1 mg/mL* under section 2.1.3. In your firm's design history file your risk analysis conducted for the finished 1 mL epinephrine syringe device does not evaluate the risk levels for the eight risks identified by your firm. Additionally, one of the mitigations listed for risk of particulates is "incoming materials controls". Your firm's supplier control's do not adequately evaluate your supplier's capabilities of meeting the supplier requirements established by your firm, including technical and regulatory requirements. Your firm's supplier of syringes for this combination product was not subject to a quality agreement and did not provide evidence to support their abilities to meet your firm's established requirements during their initial self-audit approved on 02/26/2019.

**BPI'S RESPONSE TO OBSERVATION 3:**

BPI acknowledges and accepts the investigator's observation.

BPI would like to clarify to the Agency that the risk assessment using qualitative tool (high, medium, and low terminology) was performed for the glass syringe and rubber plunger as part of the Product Development Report No. IPT-R-I11 "Epinephrine Injection, USP 1 mg/mL" under Section 2.1.3 (refer to Exhibit – 3.1 for a copy of Section 2.1.3 – only pages 1, 25, 26, and 27 are included in this exhibit; refer to Exhibit 4.1 for a copy of the entire Product Development Report No. IPT-R-I11).

As part of product design for Epinephrine Injection, USP 1 mg/mL, it was determined that the particulate matter, bacterial endotoxin (BET), and sterility of the syringe and rubber plunger pose "high" risk level, hence necessary mitigation controls were established to monitor these risks in a consistent manner (refer to below Table 1 for details). Based on thorough evaluation of these critical quality attributes impacting directly the product quality, it was understood that this high risk could be mitigated by performing adequate internal testing of incoming syringes and rubber plungers prior to release and use for production. In addition, it was defined during product development that the final finished product also needed to be tested for particulate matter,

bacterial endotoxin (BET), and sterility as part of the release specifications to ensure patient safety during usage.

Table 1 – Incoming Materials and Finished Product Testing Controls

| Item | Test | Specification | BPI Internal Acceptance Criteria | USP Acceptance Criteria |
|---|---|---|---|---|
| Syringe | Particulate Matter | SPC I3021 Particles ≥ 10µm | NMT 600 particles per container (10% of USP <788>) | NMT 6000 |
| | | Particles ≥ 25µm | NMT 60 particles per container (10% of USP <788>) | NMT 600 |
| | Bacterial Endotoxins Test | SPC I3021 | NMT 0.25 EU / mL | NMT 0.25 EU / mL, equal to Water For Injection |
| | Sterility Test | SPC I3021 | No evidence of microbial growth | No evidence of microbial growth |
| Rubber Plunger | Particulate Matter | SPC I3020 Particles ≥ 10µm | NMT 600 particles per container (10% of USP <788>) | NMT 6000 |
| | | Particles ≥ 25µm | NMT 60 particles per container (10% of USP <788>) | NMT 600 |
| | Bacterial Endotoxins Test | SPC I3020 | NMT 0.25 EU / mL | NMT 0.25 EU / mL, equal to Water For Injection |
| | Sterility Test | SPC I3020 | No evidence of microbial growth | No evidence of microbial growth |
| Finished Product | Particulate Matter | SPC I117 Particles ≥ 10µm | NMT 6000 per container | NMT 6000 per container |
| | | Particles ≥ 25µm | NMT 600 per container | NMT 600 per container |
| | Bacterial Endotoxins Test | SPC I117 | NMT 40 E.U. / mg of Epinephrine | NMT 357.0 EU/mg of Epinephrine, refer USP monograph |
| | Sterility Test | SPC I117 | No evidence of microbial growth | No evidence of microbial growth |

BPI performed risk analysis as per the FDA Guidance for Industry and FDA Staff: Current Good Manufacturing Practice Requirements for Combination Products FINAL GUIDANCE, January 2017, specified in iii. Risk Analysis page 44. BPI believes risk levels, either qualitative or quantitative, can be performed. Quantitative analysis is recommended in order to evaluate if mitigations are required or not, but BPI has implemented mitigations in this case nevertheless to ensure there is no negative impact to product quality.

BPI further reviewed the SOP IGN-035 "Handling of Combination Products" and improvements were made to provide additional instructions on risk analysis related to manufacturing as well as use-related. The revised SOP was made effective on 05/20/21 as Revision No. 03; all users of this SOP were part of the review and approval process (refer to Exhibit – 3.2 for a copy of the revised SOP along with the respective change control). BPI believes that clearer instructions on this SOP would help to assess better the risks associated as part of product design going forward.

Moreover, the combination product document associated with the design of epinephrine pre-filled syringes "Design Controls for Epinephrine Injection, USP 1 mg/mL (1 mL Syringe)", Section No. CP-I11-02, was revised to perform the risk analysis with quantitative risk levels for manufacturing related items of this mentioned product inline with the revised SOP IGN-035. Refer to Exhibit – 4.4 for copy of the revised section.

Additionally, a new section related to the combination product associated with the use-related risk analysis of epinephrine pre-filled syringes "Use-Related Risk Analysis for Epinephrine Injection, USP 1 mg / mL (1 mL Syringe)", Section CP-I11-08, was created to evaluate the use-related risk analysis linked with this mentioned product inline with the revised SOP IGN-035. Refer to Exhibit – 3.3 for copy of the revised section.

On the other hand, it is important to mention that BPI has diligently approved and re-qualified all vendors associated with the cGMP operations, including Schott Schweiz AG which is the supplier of the syringes, to ensure these are evaluated on a periodic basis to confirm their capabilities of meeting BPI requirements. Furthermore, BPI has worked systematically to generate the quality agreement between BPI and Schott Schweiz AG and to approve it in the quality system before the commercial manufacturing of the epinephrine pre-filled syringes product, in agreement with the internal company standards. The quality agreement was provided to the FDA investigators on 04/23/21 during the inspection. Refer to the responses for Observation 2 and Observation 5 to get a clearer and detailed understanding of the available controls at BPI for vendor evaluation and for quality agreements.

Finally, BPI would like to conclude that the hazards, risks, and mitigations associated with the use of the epinephrine pre-filled syringes combination product were further discussed and clarified, and it is believed that this document now reflects a more thorough risk analysis according to the product design and intended use.

**OBSERVATION 4:**

Procedures for design transfer have not been adequately established.

Specifically, your firm's design history file for your 1 mL epinephrine syringe combination product did not contain a documented design transfer that supported the device's design was correctly translated into product specifications. Under design transfer your firm documents "there is no transfer involved".

**BPI'S RESPONSE TO OBSERVATION 4:**

BPI acknowledges and accepts the investigator's observation. However, BPI would like to clarify to the Agency the design transfer activities to support the device's design and how BPI has performed this activity.

As a general policy, any product development activity is performed following Quality by Design (QbD) concepts as per US FDA guidance, which includes identification of raw materials and container closure system components, such as syringes and plungers, conducting of several compatibility studies, formulation developments, laboratory experimental batches manufacturing, risk assessments of the formulation variables, manufacturing process developments, initial risk assessments of the drug product manufacturing process, establishment of mitigation controls, and execution of exhibit batches (stability batch) manufacturing and testing activities.

As part of this process, various risk analyses are conducted, necessary specifications are established, test methods, batch manufacturing records, batch packaging records, and stability protocols are generated, among others, and finally technology transfer is executed to transition the product from research and development to production.

Specifically, for Epinephrine Injection, USP 1 mg/mL syringe product all these activities are performed and explicitly written in the Product Development Report (PDR) for this mentioned product (Document No. IPT-R-I11 – refer to Exhibit – 4.1). As the combination product requires Design Controls as per 21 CFR Part 4 Regulation of Combination Products, Guidance for Industry and FDA Staff: Current Good Manufacturing Practice Requirements for Combination Products FINAL GUIDANCE, January 2017, BPI used the activities performed as per above mentioned PDR as a reference and guidance to determine the combination product documentation.

As all design transfer activates were conducted as per the PDR and three batches of Epinephrine Injection, USP 1 mg / mL Pre-Filled Syringes (Batch Numbers I117R002, I117R003, and I117R004) were manufactured and tested for all critical quality attributes per approved

specifications, it was found that the combination product meets the pre-determined specifications. However, BPI accidentally missed to explicitly write the design transfer activity in the first version of the Design Controls document, Section No. CP-I11-02, Revision 01 (refer to Exhibit – 4.2 for copy of this section), and accepts that this unwanted situation created a gap in understanding the design transfer strategy utilized by BPI. From discussions with FDA investigator, BPI modified the Design Controls document, Section No. CP-I11-02, Revision 02, to incorporate the proper documentation associated with design transfer improvements according to the Product Development Report IPT-R-I11 (refer to Exhibit – 4.3 for a copy of the revised section). This revised section was provided to the FDA investigators during the inspection.

As a further assurance and as part of this observation, BPI proactively reviewed again the Design Controls document, Section No. CP-I11-02, Revision 02, specifically design transfer topic, and identified an extra enhancement in regards to making reference of internal SOPs associated with product development procedures, and to acknowledge the adequacy of the design transfer for the epinephrine pre-filled syringes combination product based on the acceptable results of three batches meeting pre-determined specifications and proving the overall design controls established and design transfer are effective. Refer to Exhibit – 4.4 for a copy of the revised Section No. CP-I11-02, Revision 03, Effective Date 05/20/21.

In conclusion, BPI acknowledges the inadvertent gap created in the Design Controls document, Section No. CP-I11-02, Revision 01, associated with the design transfer, even though the available standard SOP IGN-035 "Handling of Combination Products" was appropriate and included the expected discussion on this topic. Furthermore, BPI commits to be more attentive whenever creating any combination product section in the future for any new product to make sure information is accurate and precise reflecting the company's strategy from product development to the intended production environment.

**OBSERVATION 5:**

The type and extent of control to be exercised over the product and suppliers was not clearly defined.

Specifically, your firm did not establish a quality agreement with your supplier that defined the type and extent of control to be exercised over the sterile 1 mL syringe that is a component of your firm's sterile 1 mL epinephrine syringe combination product until 04/22/2021. This is required per SOP IGN-034 Section 6.3.6 upon vendor approval. Your firm's supplier of sterile 1 mL syringes was approved on 02/26/2019.

**BPI'S RESPONSE TO OBSERVATION 5:**

BPI acknowledges and accepts the investigator's observation. However, BPI would like to explain to the Agency all the available procedures that were in place at the time of the FDA inspection to define and execute the type and extent of control to be exercised over vendors and components were met.

New vendors are initially approved in the quality system following the requirements documented in SOPs IPC-001 "Purchasing System" and IGN-034 "Vendor Management System". Then, vendors are re-qualified in a periodic manner as per the guidelines written in both mentioned procedures. Both the initial and re-qualification exercises are well defined to assess the adequacy of the vendor performance at all times.

Similarly, new components are initially approved in the quality system following the requirements documented in SOP IGN-003 "Creation and Modification of Code Numbers and National Drug Code Numbers (NDC)"; the components are first introduced in the company for research and development purposes. Specification for each component is generated in the quality system describing all incoming controls to be exercised during physical, chemical, and microbiological testing as part of full testing, retesting, and reduced testing. Moreover, each component is introduced to the qualification program stipulated in SOP IQA-010 "Vendor Qualification Program" defining the type and extent of control to be exercised over the specific component during initial full testing and subsequent reduced testing.

Refer to Exhibit – 5.1 for copy of mentioned SOPs IPC-001 Revision No. 04, IGN-034 Revision No. 04, IGN-003 Revision No. 01, and IQA-010 Revision No. 03 that were effective at the time the FDA inspection was conducted.

In regards to the observation noted by the FDA, specifically related to the Clear Glass Syringes Ready to Use Packaging Component, BPI Code Number I3021, supplied by SCHOTT Schweiz AG, BPI would like to clarify the execution of all available procedures that were in place at the

time of the FDA inspection to define and execute the type and extent of control to be exercised for this vendor and this syringe, consistent with the quality system requirements explained above.

SCHOTT Schweiz AG was initially approved in the quality system on 02/26/19 (refer to Exhibit – 5.2). This vendor was re-qualified in the quality system on 02/17/21 (refer to Exhibit – 5.3), based on two years re-qualification period.

Clear Glass Syringes Ready to Use Packaging Component code number creation was approved in the quality system on 11/11/19 with material type as "Research and Development" and under Code Number I3021 (refer to Exhibit – 5.4).

Specification for Code Number I3021 was initially approved on 12/27/19 as Revision No. 01 (refer to Exhibit – 5.5). This specification clearly defined the full testing, reduced testing, and retesting requirements to be utilized for the type and extent of control of this component during release.

Based on SOP IQA-010, full testing needs to be executed per specification on three consecutive different vendor lots received by BPI; each lot tested needs to conform to established specifications in order to qualify this component for reduced testing. Precisely, BPI has received three shipments of component Code Number I3021 from SCHOTT Schweiz AG and performed successful full testing accordingly to the specification. As of now, this component is still classified as "Full Testing" since one extra consecutive different vendor lot is needed to be received and tested as part of the "Reduced Testing" certification (refer to Exhibit – 5.6 for the full testing data of the three shipments).

The above confirms that BPI has determined clear procedures to define the type and extent of control to be exercised on vendors and components, has executed the procedures in place with SCHOTT Schweiz AG and with the Clear Glass Syringes Ready to Use Packaging Component (Code Number I3021), and hence has full understanding and control about the quality of this component handled by the firm.

On the other hand, BPI has determined the need to generate quality agreements for some vendors depending on the type of component that is being supplied. These quality agreements are intended to provide an overall approach about the implementation of oversight and controls between parties involved with the purpose of establishing each party's key specific roles and manufacturing activities to comply with cGMP. Specifically, quality agreements for ready to use pre-sterile packaging components (i.e., syringes) are only required at BPI for commercial materials (refer to Exhibit – 5.1 for copy of SOPs IPC-001 and IGN-034).

As of today, all components supplied to BPI by SCHOTT Schweiz AG are still categorized under "Research and Development", including the Clear Glass Syringes Ready to Use Packaging

Component (Code Number I3021), and all shipments received so far from this mentioned vendor have only been used for the manufacturing of research and development lots. Accordingly, it is evident that the component pointed out by the Agency is not approved for commercial use until now and therefore the quality agreement was technically not needed yet based on internal BPI's standards stated in SOPs IPC-001 and IGN-034.

BPI started working with SCHOTT Schweiz AG in September 2020 in order to generate the quality agreement between both firms as part of completeness of tasks for potential and upcoming commercial use of this vendor and associated components. For some administrative reasons, SCHOTT Schweiz AG took longer time to finalize this quality agreement despite the frequent and diligent follow up made by BPI. Finally, the quality agreement was approved on 04/22/21 and confirmed to be adequate to initiate the further control of the upcoming commercial shipments. The same was also provided to the investigator during the inspection.

As explained in this response, the Clear Glass Syringes Ready to Use Packaging Component (Code Number I3021) has not been internally approved for commercial use although all incoming and in-process controls for the shipments received so far have been meticulously monitored during release and use and found them to be acceptable and appropriate ratifying the quality and performance of SCHOTT Schweiz AG. Based on all the facts mentioned as part of this answer, BPI believes that there is no negative impact on SCHOTT Schweiz AG and on the Clear Glass Syringes Ready to Use Packaging Component (Code Number I3021) by not having the quality agreement approved before 04/22/21 since the vendor and the component are still under research and development use and BPI has followed strictly its internal standards and controls.

It is important to inform to the Agency that all these explanations and evidences were shown and discussed with the FDA investigator during the inspection.

Nonetheless as part of this observation, BPI performed a thorough evaluation of all commercial materials and components and confirmed that adequate quality agreements are in place and approved prior to any commercial distribution of the associated products, inline with the requirements of SOPs IPC-001 and IGN-034. This finding further validates that BPI has been following its internal controls at all times.

As a further assurance, BPI revisited the wording of its controls for quality agreements and identified an opportunity for improvement to present in a more explicit manner the current expectations and practices on this topic. Consequently, BPI has revised SOP IGN-034 "Vendor Management System" in the quality system to clarify the requirements of quality agreements, including the ones that are required for materials and components transitioning from research and development to commercial use. The revised SOP was made effective on 05/18/21 as Revision No. 05; all users of this SOP were part of the review and approval process (refer to Exhibit – 5.7 for a copy of the revised SOP along with the respective change control). BPI

believes that clearer instructions on this SOP would contribute to avoid misinterpretations about the need and timeliness of the quality agreements, whenever applicable.

Finally, BPI believes that procedures that defined the type and extent of control to be exercised over vendors and components that were incorporated into the quality system from day one and executed effectively, did not require a quality agreement between BPI and SCHOTT Schweiz AG to be in place since 02/26/19, and that quality agreement between both mentioned firms was already approved on 04/22/21 prior to the release of the associated commercial product, reaffirming that BPI has followed its SOPs and has operational systems to control vendors and components intended for commercial purposes.

# 10B

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440

## APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New OUTSOURCING FACILITY
☐ Ownership Change (Provide current license number if making changes:) OUT_____
☐ 503a OR ☒ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1-3 & 4
☐ Partnership - Pages 1-3 & 6
☒ Non Publicly Traded Corporation – Pages 1-3 & 5
☐ Sole Owner – Pages 1-3 & 7

**GENERAL INFORMATION to be completed by all types of ownership**

Facility Name: Hikma Injectables USA Inc.

Physical Address: 36 Stults Road

City: Dayton State: NJ Zip Code: 08810

Telephone: 732-380-4440 Fax: _____

Toll Free Number: 877-845-0689 (Required per NAC 639.708)

E-mail: 503Blicensing@hikma.com Website: hikma503B.com

Supervising Pharmacist: Cindy L. Mitman ✓ Nevada License #: 19891 ✓

**SERVICES PROVIDED**

Yes/No

☐ ☒ Parenteral
☒ ☐ Sterile Compounding
☐ ☒ Non Sterile Compounding
☐ ☒ Mail Service Sterile Compounding
☐ ☒ Other Services: _____

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only Date Processed: _____ Amount: 500.00 CK-1484015977

**APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY** **Page 2**

FEI Number (From FDA application): 3022897129 ✓

Please provide the name of the facility as registered with the FDA and the registration number:
Hikma Injectables USA Inc.

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
Hikma 503B

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Cindy L. Mitman Nevada License Number: 19891

A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: NV 20212147192

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

**APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3**

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☐

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Omar F. Alkhrisat
Print Name of Authorized Person

6/28/2022
Date

**APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY** **Page 5**

**OWNERSHIP IS A NON PUBLICY TRADED CORPORATION**

State of Incorporation: Delaware

Parent Company if any: EuroHealth (U.S.A.), Inc.

Address: 200 Connell Drive

City: Berkeley Heights State: NJ Zip: 07922

Telephone: 856-489-2110 Fax: _____

Contact Person: George J. Munch III.

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) N/A
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. N/A

3) What was the price paid per share? N/A

4) What date did the corporation actually receive the cash assets? N/A

5) Provide a copy of the corporation's stock register evidencing the above information

## Include with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

**Section 1: General Information**

Pharmacy Name: Hikma Injectables USA Inc.

NV Pharmacy or Outsourcing facility license # (if applicable): N/A

Physical Address: 36 Stults Road

City: Dayton State: NJ Zip: 08810

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 732-380-4440 Toll Free # (NAC 639.708, NRS 639.23286): 877-845-0689

Fax: _____ Contact Email: 503BLicensing@hikma.com

Website: Hikma503B.com

Nevada Business License # (if applicable) B202106251781526

Supervising/Managing Pharmacist Name (NRS 639.220): Cindy Mitman

Supervising/Managing Pharmacist NV Pharmacist Registration #: 19891

Name of Person with direct knowledge of compounding procedures: Cindy Mitman

Email of Person with direct knowledge of compounding procedures: CMitman@hikma.com

Telephone of Person with direct knowledge of compounding procedures: 856-266-3131

**Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)**

1. What risk level sterile compounding will your facility be performing (check all that apply)? ■ Low ■ Medium ☐ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ■ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
See Attached Product List.

4. Will you be utilizing beyond use dates in excess of USP-797? ■ Yes ☐ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:
All products have completed stability studies supporting their BUD. Annual stability studies are ongoing and confirm the BUD. Stability studies include a stability indicating method for potency, identification, appearance, pH, visible particles, sub-visible particles, osmolarity, sterility and endotoxin testing.

6. What laboratory performs this additional testing?
Name: Hikma Injectables USA Inc.
Address: 36 Stults Road
City: Dayton State: NJ Zip: 08810
Telephone: 732-380-4440

7. What is your procedure for visual inspection of compounded sterile products?
100% visual inspection is performed by trained and qualified inspectors. They are trained for identifying particles as well as defects, overfill, underfill and leaking. They utilize a black and white box and inspect for 5 seconds on each background. They invert the syringes or bags to look at them from all angles. Visual inspection is followed by an acceptable quality limit or AQL to test a smaller portion of the batch for a second time.

8. How often do you perform glove fingertip and medial fill testing?

Glove fingertip and wrist sampling is performed after the different processes within each batch. Media fill is completed every 6 months for processes and once per year for personnel. Initial qualification requires a triplicate media fill.

9. What is your policy if an employee fails a glove fingertip or media-fill test?

Gloved fingertip as far as a gowning qualification would require a compounder to retrain and requalify. They would not be allowed entry into the cleanroom with a failed gowning qualification. Gloved fingertip sampling that fails during production would cause a rejection in a batch and require an investigation. A failed media fill test would require an investigation, a retraining and a repeat of the media fill before being qualified to compound.

10. Describe your initial and annual training program for all personnel performing sterile compounding:

Personnel who compound are required to complete all SOPs related to gowning and compounding. They are them required to become gown qualified. Upon successful completion of gowning qualification, personnel train in a LAFH utilizing all of the same equipment that is used in the cleanroom. They learns hands on training with a qualified trainer and are required to perform each process first through observation, followed by performing with assistance and finally performing without assistance. Once all requirements are met, personnel participate in a media fill and must pass with no turbid units to be qualified. Initial media fill requirements are to be performed in triplicate. Annual requirements are to complete one media fill per year. Process media fills are required every six months, so technicians often participate in media fills multiple times per year.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

The primary engineering controls (ISO 5 laminar airflow hoods) are cleaned on per batch and daily bases. Prior to production use for a batch, the hood and compounding equipment are cleaned with a sporicidal agent (Spor-Klenz RTU®). After the contact time is met, the hood and compounding equipment are again cleaned with sterile 70% isopropyl alcohol before batch processing begins. On a daily basis, the hoods and compounding equipment, as well as accessories, carts, tables, and floors, are cleaned with a phenolic disinfectant (LpH® III st or Vesphene ® III st, depending on the rotation plan). On a weekly basis, the same surfaces plus the walls are cleaned with the phenolic disinfectant. And on a monthly basis, the same surfaces plus the walls and ceilings are cleaned with Spor-Klenz RTU®.

12. Who performs the sterile compounding process at your facility?

Trained and qualified compounders perform the sterile compounding.

13. Who is responsible and accountable for the sterile compounding process at your facility?

The pharmacist in charge is responsible for the sterile compounding process. Quality assurance provides oversight in the cleanroom.

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

1. All products are packaged with a bubble-wrap liner inside the intermediate carton to ensure the product is not damaged during storage and transit to the customer.
2. Any additional space inside the shipper box is filled with paper filling to ensure no movement of the product during transit.
3. All intermediate cartons for product is sealed with tamper evident tape to ensure if there's any tampering of product it'll be visibly noticeable.
4. The only label visible on the outside of the shipper box is the shipper label (FedEx Label). No labels identifying what is inside the box is present on the outside of the shipper box.

| **Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)** | | |
|---|---|---|
| 1. What type of primary engineering controls will you be using in your facility?<br>N/A | | |
| 2. Is your BSC or CACI vented 100% to the outside? | ☐ Yes | ☐ No |
| 3. Do you have a negative pressure buffer room at your facility? | ☐ Yes | ☐ No |
| 4. Will you be compounding with antineoplastic HDs or HD API? | ☐ Yes | ☐ No |
| 5. If yes, are the drugs stored in an externally ventilated, negative pressure room? | ☐ Yes | ☐ No |
| 6. Will you be utilizing a closed system transfer device? | ☐ Yes | ☐ No |
| 7. If yes, list the name of the device: | | |
| 8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers? | | |
| 9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs? | | |

| **Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)** |
|---|
| 1. List the specific high risk sterile products that your facility compounds: |
| 2. What sterilization methods are utilized at your facility? |
| 3. Does your facility utilize biological indicators? ☐ Yes ☐ No |
| 4. If yes, describe how they are utilized: |

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Cindy Mitman

Name of Person who Completed the Form

Director of Quality Systems and Compliance / Pharmacist-in-Charge

Title

Cindy Mitman

Signature (copies or stamps not accepted)

14 Nov 2022

Date

| **Board Use Only** | Date Received: 11-21-22 Date Approved: _____ Approved By: _____ |
|---|---|

# Hikma Injectables USA Inc.

## Officer/Director Information

| Name | Title | Location |
|---|---|---|
| **Said Darwazah** | Director | Industrial Area, Bayader Wadi El-Seer, P.O. Box 182400, Amman 11118, Jordan |
| **Hussein Arkhagha** | Director | Industrial Area, Bayader Wadi El-Seer, P.O. Box 182400, Amman 11118, Jordan |
| **Riad Mechlaoui** | Director | Estrada do Rio da Mó, 8, A/B - Fervença 2705-906 Terrugem SNT – Portugal |
| **Omar Khrisat** | President | 2 Esterbrook Lane Cherry Hill, NJ 08003 |
| **Yogeshkumar Akhani** | Chief Financial Officer | 200 Connell Drive Berkeley Heights, NJ 07922 |
| **George J. Muench III** | Treasurer | 2 Esterbrook Lane Cherry Hill, NJ 08003 |
| **Turlough Gorman** | Secretary | 200 Connell Drive Berkeley Heights, NJ 07922 |
| **Ossama Hussein** | Assistant Secretary | 2 Esterbrook Lane Cherry Hill, NJ 08003 |

STATE OF UTAH
DEPARTMENT OF COMMERCE
ACTIVE LICENSE

Hikma Injectables USA Inc.

EFFECTIVE 06/17/2022
EXPIRATION 09/30/2023

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

12839315-1710 Pharmacy - Class C
12839315-8913 Dispensing Controlled Substance License
Manufacturer

DBA: HIKMA 503B

**IMPORTANT LICENSURE REMINDERS:**

- Your license is valid until the expiration date listed on this form. Approximately 60 days prior to this expiration you will receive a renewal notice in the mail.
- Please note the address listed below. This is your public address of record for the division, and all future correspondence from the division will be mailed to this address. If you move, it is your responsibility to notify us directly of the change. Maintaining your current address with us is the easiest way to ensure continuous licensure.

HIKMA INJECTABLES USA INC.
36 STULTS ROAD
DAYTON NJ 08810

Please visit our web site at www.dopl.utah.gov should you have any questions in the future.

STATE OF UTAH
DEPARTMENT OF COMMERCE
DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING
ACTIVE LICENSE

EFFECTIVE DATE: 06/17/2022
EXPIRATION DATE: 09/30/2023
ISSUED TO: Hikma Injectables USA Inc.
36 Stults Road
Dayton NJ 08810

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)
12839315-1710 Pharmacy - Class C
12839315-8913 Dispensing Controlled Substance License
Manufacturer
DBAs: HIKMA 503B

Form #1

***STATE OF NEW JERSEY***
***DEPARTMENT OF THE TREASURY***
***DIVISION OF REVENUE AND ENTERPRISE SERVICES***
***SHORT FORM STANDING***

***HIKMA INJECTABLES USA INC.***
*0101056405*

*I, the Treasurer of the State of New Jersey, do hereby certify that the above-named Delaware Foreign For-Profit Corporation was registered by this office on September 24, 2020.*

*As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.*

*I further certify that the registered agent and office are:*

*C T CORPORATION SYSTEM*
*820 BEAR TAVERN ROAD*
*WEST TRENTON, NJ 08628*

*IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 5th day of April, 2023*

*Elizabeth Maher Muoio*
*State Treasurer*

*Certificate Number : 6141926495*

*Verify this certificate online at*

*https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp*

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER, ENVIRONMENTAL AND OCCUPATIONAL HEALTH SERVICE
PUBLIC HEALTH AND FOOD PROTECTION PROGRAM
P.O. BOX 369, TRENTON, NJ 08625-0369
609-826-4935

# REPORT OF INSPECTION

Assignment No **16147**

| Registration # | Category | Inspection Type | Evaluation |
|---|---|---|---|
| **5005934** | **Wholesale Drug/Medical Device** | **Initial** | **Satisfactory** |

| Name of Owner or Corporation | Trade Name | Activity |
|---|---|---|
| **Eurohealth (U.S.A.), Inc.** | **Hikma Injectables USA, Inc.** | **Wholesaler/Warehouse** |

| Establishment Street Address | City | ZIP | County |
|---|---|---|---|
| **36 Stults Road** | **Dayton** | **08810** | **Middlesex** |

| Establishment Mailing Address (if different) | Phone Number | Fax Number |
|---|---|---|
| | **732-380-4501** | |

| Name and Title of Inspecting Official | REHS Lic. # | Operational Status | Embargo | Reinspect on or After |
|---|---|---|---|---|
| **Joe Eldridge** | | **Pre-Operational** | **------** | |

| Name and Title of Designated Representative | Email |
|---|---|
| **Michael Moore** | **jkalis@hikma.com** |

Products
☒ Prescription Drugs ☒ OTC Drugs ☐ Class I Medical Devices ☐ Class II Medical Devices ☐ Class III Medical Devices

TIME/ACTIVITY REPORT (1-TRAVEL, 2-INSPECTION, 3-ADMINISTRATION, 4-PERSONAL) TOTAL HOURS: 00.00 + -

| DATE | CODE | BEGIN | END | CODE | BEGIN | END | CODE | BEGIN | END |
|---|---|---|---|---|---|---|---|---|---|
| 04/27/2021 | 1 | 10:00 | 11:00 | 2 | 11:00 | 12:00 | 1 | 12:00 | 01:00 |
| | | | | | | | | | |

| | | YES | NO | N/A |
|---|---|---|---|---|
| | **N.J.A.C. 8:21-3A.7 Personnel Requirements** | | | |
| | Personnel employed by a wholesale distributor have appropriate education and/or experience to assume responsibility for positions related to compliance with State registration requirements | ☒ | ☐ | ☐ |
| Note | | | | |
| | **N.J.A.C. 8:21-3A.8 Facility** *Facilities at which drugs are stored, warehoused, handled, held, offered, marketed or displayed:* | | | |
| (a) 1 | Of suitable size and construction to facilitate cleaning, maintenance, and proper operations | ☒ | ☐ | ☐ |
| (a) 2 | Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions | ☒ | ☐ | ☐ |
| (a) 3 | Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened | ☒ | ☐ | ☐ |
| (a) 4 | Maintained in a clean and orderly condition | ☒ | ☐ | ☐ |
| (a) 5 | Free from infestation by insects, rodents, birds, or vermin of any kind | ☒ | ☐ | ☐ |
| Note | | | | |

# NEW JERSEY REPORT OF INSPECTION

| | | YES | NO | N/A |
|---|---|---|---|---|
| | **N.J.A.C. 8:21-3A.9 Security** | | | |
| (a) | Facility is secured from unauthorized entry | ☒ | ☐ | ☐ |
| (a) 1 | Access from outside premises is kept to a minimum and is well controlled | ☒ | ☐ | ☐ |
| (a) 2 | The outside perimeter of the premises is well-lighted | ☒ | ☐ | ☐ |
| (a) 3 | Entry into areas where drugs are held shall be limited to authorized personnel | ☒ | ☐ | ☐ |
| (b) | All facilities are equipped with an alarm system to detect entry after hours | ☒ | ☐ | ☐ |
| (c) | Facilities are equipped with a security system that provides suitable protection against theft and diversion. When applicable, the security system provides protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records | ☒ | ☐ | ☐ |
| Note | | | | |
| | **N.J.A.C. 8:21-3A.10 Storage** | | | |
| (a) | All drugs are stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, of the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF). | ☒ | ☐ | ☐ |
| (b) | If no storage requirements are established for a drug, the drug is held at controlled room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected | ☒ | ☐ | ☐ |
| (c) | Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs are utilized to document proper storage of drugs | ☒ | ☐ | ☐ |
| (d) | For prescription drugs a record is maintained that includes the date, time, thermometer temperature, and the initials of the person recording the data | ☒ | ☐ | ☐ |
| Note | | | | |
| | **N.J.A.C. 8:21-3A.11 Examination of Materials** | | | |
| (a) | Upon receipt, each outside shipping container is visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination is adequate to reveal container damage that would suggest possible contamination or other damage to the contents. | ☒ | ☐ | ☐ |
| (b) | Each outgoing shipment is carefully inspected for identity of the prescription drug products | ☒ | ☐ | ☐ |

# NEW JERSEY REPORT OF INSPECTION

| | | YES | NO | N/A |
|---|---|---|---|---|
| | and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions. | | | |
| Note | | | | |
| | **N.J.A.C. 8:21-3A.12 Returned, Damaged and Outdated Drugs** | | | |
| (a) | Outdated, damaged, deteriorated, misbranded, or adulterated drugs are quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier | ☒ | ☐ | ☐ |
| (b) | Drugs whose immediate or sealed outer or sealed secondary containers have been opened or used are identified as such, quarantined and physically separated from other drugs until they are either destroyed or returned to the supplier | ☒ | ☐ | ☐ |
| (c) | If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug is destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity | ☒ | ☐ | ☐ |
| Note | | | | |
| | **N.J.A.C. 8:21-3A.13 Recordkeeping** | | | |
| (a) | Inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs are maintained | ☒ | ☐ | ☐ |
| (a) 1 | Source of drugs, name and principal address of the seller or transferor, and address from which drugs were shipped are maintained | ☒ | ☐ | ☐ |
| (a) 2-3 | Identity and quantity of drugs received and distributed/disposed, date of receipt and distribution, disposal. | ☒ | ☐ | ☐ |
| (a) 5 | A complete and accurate annual record of all stock of drugs on hand. | ☒ | ☐ | ☐ |
| (d) | An ongoing listing of all retail and wholesale establishments with whom they do business. | ☒ | ☐ | ☐ |
| Note | | | | |
| | **N.J.A.C. 8:21-3A.14 Due Diligence**<br>*Firm is performing due diligence of other wholesale establishments with whom they do business, which requires that prior to the initial purchase or acquisition of drugs from another wholesale distributor, a wholesale distributor shall obtain the following information from the selling wholesale distributor:* | | | |
| (a) 1 | Copies of all state and Federal regulatory licenses and registrations | ☒ | ☐ | ☐ |
| (a) 2 | The wholesale distributor's most recent facility inspection reports | ☒ | ☐ | ☐ |
| (a) 3 | A list of other names under which the wholesale distributor is doing business or by which the wholesale distributor was formerly known | ☒ | ☐ | ☐ |

# NEW JERSEY REPORT OF INSPECTION

| | | YES | NO | N/A |
|---|---|---|---|---|
| (a) 4 | A list of corporate officers and managerial employees and designated representatives | ☒ | ☐ | ☐ |
| (a) 5 | A verification of the selling wholesale distributor's status as an authorized distributor of record, if applicable. | ☒ | ☐ | ☐ |
| (b) | At least annually, a wholesale distributor that purchases prescription drugs from another wholesale distributor updates the information set forth in (a) 1-5 above. | ☒ | ☐ | ☐ |
| (c) | No purchases were placed from any storage facility, manufacturer or wholesale distributor not having a current license or registration within the jurisdiction of the establishment location from where product is purchased. | ☒ | ☐ | ☐ |
| (d) | No purchase or acquisition has been made from a firm that has not provided complete information as set forth in (a) 1-5 above. | ☒ | ☐ | ☐ |
| Note | | | | |
| | **N.J.A.C. 8:21-3A.15 Availability of Records and Inventories** | | | |
| (a) | Records and inventories, including those related to salvage and reprocessing, are made available for inspection and photocopying by authorized Federal, State, or local law enforcement agency officials for a period of 3 years after the date of their creation | ☒ | ☐ | ☐ |
| (b) | Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means are readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable are made available for inspection within 2 working days of a request by an authorized official of a Federal, State, or local law enforcement agency | ☒ | ☐ | ☐ |
| Note | | | | |
| | **N.J.A.C. 8:21-3A.16 Policies and Procedures** | | | |
| (a) | Firm established and follows written policies and procedures for the receipt, security, storage, inventory, and distribution of drugs | ☒ | ☐ | ☐ |
| (a) | Firm has policies for identifying, recording and reporting losses or thefts and correcting errors in inventories | ☒ | ☐ | ☐ |
| (a) 1 | Firm has a procedure where oldest stock is distributed first. | ☒ | ☐ | ☐ |
| (a) 2 | Firm has a procedure for handling recalls/withdrawals of drugs. | ☒ | ☐ | ☐ |
| (a) 3 | Firm has a procedure for preparation, protection and proper handling of any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster | ☒ | ☐ | ☐ |
| (a) 4 | Firm has a procedure for handling return of outdated drugs; segregation and written documentation of disposal, by either returning the drug to the manufacturer or destruction of the drug. This documentation shall be maintained for 2 years after disposition of the outdated drugs. | ☒ | ☐ | ☐ |

# NEW JERSEY REPORT OF INSPECTION

| | | YES | NO | N/A |
|---|---|---|---|---|
| Note | | | | |
| | **N.J.A.C. 8:21-3A.17 List of Responsible Persons** | | | |
| | A current list of officers, directors, managers, and other personnel in charge of wholesale distribution, storage, and handling of prescription drugs is maintained at the firm | ☒ | ☐ | ☐ |
| | Description of duties and qualifications of personnel is maintained at the firm | ☒ | ☐ | ☐ |
| Note | | | | |
| | **N.J.A.C. 8:21-3A.19 Salvage; Reprocessing** | | | |
| | Salvaging and reprocessing operation is in compliance with 21 CFR 207, 210, 211 | ☒ | ☐ | ☐ |
| Note | | | | |

Joe Eldridge

Inspector's Signature

| State | Business_Name_on_License | License_Number | License_Type | License_Original_Issue_ | License_Expiration_D | License_Status |
|---|---|---|---|---|---|---|
| Federal | Hikma Injectables USA Inc. | 117939054 | Human Drug Compounding Outsourcing Facility | 9/15/2021 | | |
| Federal | Hikma Injectables USA Inc. | RH0603490 | DEA Certificate- Manufacturing | 9/22/2021 | 10/31/2022 | Active |
| New Jersey | Hikma Injectables USA Inc. | 5005934 | Environmental Health Service (NJDOH) | | 1/31/2023 | Active |
| New Jersey | Hikma Injectables USA Inc. | 10CM00035600 | Controlled Dangerous Substance-Manufacturer | | 3/31/2023 | Active |
| New Jersey | Hikma Injectables USA Inc. | 10CW00055200 | Controlled Dangerous Substance-Wholesale/Distributer | | 3/31/2023 | Active |
| Montana | Hikma Injectables USA Inc. | PHA-WDD-LIC-83503 | Wholesale Drug Distributor | | 11/30/2022 | Active |
| Hawaii | Hikma Injectables USA Inc. | E15823 | Registration for Controlled Substances | | 10/31/2022 | Active |
| Pennsylvania | Hikma Injectables USA Inc. | 1000004236 | Manufacturer- Controlled Substance | 11/30/2021 | 11/30/2022 | Active |
| Wisconsin | Hikma Injectables USA Inc. | | Exemption | | | |
| Louisiana | Hikma Injectables USA Inc. | 10450 | Distributor of Legend Drugs Or Legend Devices | 1/4/2022 | 12/31/2022 | Active |
| Louisiana | Hikma 503B | CDS.061906-MFR | CDS License- Manufacturer | 1/27/2022 | 1/27/2023 | Active |
| Rhode Island | Hikma Injectables USA Inc. | BIS03675 | Drug Manufacturer-Out of State | 2/21/2022 | 9/30/2022 | Active |
| Indiana | Hikma Injectables USA Inc. | | Exemption | | | |
| Georgia | Hikma 503B | PHMA000617 | Manufacturing Pharmacy | 2/17/2022 | 6/30/2023 | Active |
| Oregon | Hikma Injectables USA Inc. | M-0003685 | Manufacturer | 2/11/2022 | 9/30/2022 | Active |
| Oregon | Hikma Injectables USA Inc. | M-0003685-CS | Controlled Substance | 2/11/2022 | 9/30/2022 | Active |
| Missouri | Hikma Injectables USA Inc. | 2022011085 | Drug Outsourcer | | 10/31/2023 | Active |
| Connecticut | Hikma Injectables USA Inc. | CSM.0002102-DOS | Out of State Manufacturer of Drugs, Cosmetics and Medical Devices | 11/9/2021 | | Active |
| Washington | Hikma Injectables USA Inc. | PHWH.FX.61264000 | Pharmaceutical Wholesaler License | 4/11/2022 | 9/30/2022 | Active |
| Texas | Hikma Injectables USA Inc. | 1003370 | Food & Drug License - Controlled Substance, Prescription | 4/4/2022 | 11/3/2023 | Active |
| South Dakota | Hikma Injectables USA Inc. | 600-3422 | Wholesale | 4/20/2022 | 12/30/2022 | Active |
| Alaska | Hikma Injectables USA Inc. | 194595 | Outsourcing Facility | 5/5/2022 | 6/30/2024 | Active |
| Colorado | Hikma Injectables USA Inc. | NOF.0000012 | Non-Resident 503B Outsourcing Facility | 4/8/2022 | 10/31/2022 | Active |
| Washington DC | Hikma Injectables USA Inc. | CF2200021 | Non-Resident Manufacturer Controlled Susbstance Registration | 5/17/2022 | 5/17/2024 | Active |
| Washington DC | Hikma Injectables USA Inc. | DM2200078 | Non-Resident Manufacturer | 5/17/2022 | 5/31/2023 | Active |
| Wyoming | Hikma Injectables USA Inc. | CSB01156 | Controlled Substance Registration | 5/20/2022 | 6/30/2023 | Active |
| Wyoming | Hikma Injectables USA Inc. | WD2282 | Wholesale Distributor License | 5/20/2022 | 6/30/2023 | Active |

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 10 Waterview Blvd., 3rd Floor<br>Parsippany, NJ 07054<br>(973)331-4900 Fax:(973)331-4969<br>ORAPHARM1_RESPONSES@fda.hhs.gov | 5/23/2022-6/8/2022*<br>FEI NUMBER<br>3022897129 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael J. Moore, Senior Director Compounding Operations

| FIRM NAME | STREET ADDRESS |
|---|---|
| Hikma Injectables USA Inc | 36 Stults Rd |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Dayton, NJ 08810-1540 | Outsourcing Facility |

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:**

## OBSERVATION 1

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically:

1. Your airborne particulate monitoring program for aseptic operations is not designed and conducted to provide meaningful data to support the quality of your drug products intended to be sterile. You do not monitor airborne particulates to ISO 5 air classifications throughout aseptic operations and the orientation of the particle counter isokinetic probe is not directed into the flow of air during monitoring. For example:

   a. On 05/24/2022 during the aseptic filling of Ketamine HCL 50 mg per ml Injection, NDC 63037-137-25, Lot No.: 221430001D in cleanroom 142-6 within ISO 5 Horizontal Laminar Flow Hood No.: GE-CMP-ELH026, we observed that airborne particulate monitoring was performed only one time for approximately one minute during the operation. You do not provide scientific justification for the frequency and duration of airborne particulate monitoring performed during aseptic operations in the critical zone of the ISO 5 Horizontal Laminar Flow Hood.

   b. On 05/24/2022 during the aseptic filling of Ketamine HCL 50 mg per ml Injection, NDC 63037-137-25, Lot No.: 221430001D in cleanroom 142-6 within ISO 5 Horizontal Laminar Flow Hood No.: GE-CMP-ELH026, we observed that the orientation of the particle counter isokinetic probe was not directed into the flow of air during monitoring. The particle counter isokinetic probe was positioned nearly vertically in the horizontal laminar flow hood where

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Edmund F Mrak, Investigator<br>Samir C Gala, Investigator<br>Jay B Shah, Investigator<br>X | 6/8/2022 |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 10 Waterview Blvd., 3rd Floor<br>Parsippany, NJ 07054<br>(973)331-4900 Fax:(973)331-4969<br>ORAPHARM1_RESPONSES@fda.hhs.gov | 5/23/2022-6/8/2022*<br>FEI NUMBER<br>3022897129 |

| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | |
|---|---|
| Michael J. Moore, Senior Director Compounding Operations | |
| FIRM NAME<br>Hikma Injectables USA Inc | STREET ADDRESS<br>36 Stults Rd |
| CITY, STATE, ZIP CODE, COUNTRY<br>Dayton, NJ 08810-1540 | TYPE ESTABLISHMENT INSPECTED<br>Outsourcing Facility |

the airflow is expected to be horizontal as delivered from the HEPA filter in the back of the hood. You do not provide scientific justification for the observed orientation of the particle counter isokinetic probe.

c. Requirements written in your procedure SOPDTN15162, Routine Non-Viable particle count procedure, Effective 02/28/2022, specify an airborne particulate monitoring frequency of only one time for one minute during each aseptic compounding and filling operation to include pooling, subassembly, and syringe or IV Bag filling. You do not provide scientific justification for this frequency and duration of airborne particulate monitoring performed during aseptic operations in the critical zone of the ISO 5 Horizontal Laminar Flow Hood.

2. On 05/24/2022 during the aseptic filling of Ketamine HCL 50 mg per ml Injection, NDC 63037-137-25, Lot No.: 221430001D in cleanroom 142-6 within ISO 5 Horizontal Laminar Flow Hood No.: GE-CMP-ELH026, we observed that the passive airborne viable monitoring (settling plate) location was adjacent to the HEPA filter face in the back of the hood. You do not provide scientific justification for the observed monitoring location. Your procedure SOPDTN15121, Microbiological Environmental Monitoring of Compounding Department, Effective 02/28/2022, describes the passive airborne viable monitoring (settling plate) location as "Inside LFH, back of the workbench".

**OBSERVATION 2**

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically:

You have not evaluated the airflow pattern in all your ISO 5 Horizontal Laminar Flow Hoods under dynamic conditions simulating every aseptic operation performed in each hood during sterile-to-sterile

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE<br>Edmund F Mrak, Investigator<br>Samir C Gala, Investigator<br>Jay B Shah, Investigator | X | DATE ISSUED<br>6/8/2022 |
|---|---|---|---|

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 10 Waterview Blvd., 3rd Floor<br>Parsippany, NJ 07054<br>(973)331-4900 Fax:(973)331-4969<br>ORAPHARM1_RESPONSES@fda.hhs.gov | 5/23/2022-6/8/2022*<br>FEI NUMBER<br>3022897129 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael J. Moore, Senior Director Compounding Operations

| FIRM NAME | STREET ADDRESS |
|---|---|
| Hikma Injectables USA Inc | 36 Stults Rd |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Dayton, NJ 08810-1540 | Outsourcing Facility |

compounding and aseptic filling of your drug products intended to be sterile.
Inspectional evaluation of your ISO 5 area airflow pattern studies; Document No.: MMFDocDTN15033, Risk Assessment Regarding the Equivalency of the LFH through the process of dynamic smoke studies, Approved Date: 05/26/2022; and List of Commercial Batches Compounded related with hood smoke studies in dynamic, revealed that numerous products/lots were produced during the period 02/22/2022 to the present through aseptic operations performed in ISO 5 Horizontal Laminar Flow Hoods for which there was no direct dynamic airflow pattern evaluation. For example: Fentanyl Citrate 50 mcg/ml (100 mcg per 2 ml) in 0.9% Sodium Chloride Injection, NDC 63037-190-25, Lot No.: 220750002D, Expiry: 07/15/2022, was produced in cleanroom suite 142-7 and filled in ISO 5 Horizontal Laminar Flow Hood No.: GE-CMP-ELH025 which was not directly assessed in an airflow pattern study for the aseptic syringe filling operation.

Furthermore, your dynamic airflow pattern studies performed in ISO 5 Horizontal Laminar Flow Hoods did not consider the condition when the cleanroom suite (housing the ISO 5 Hoods) doors are opened momentarily during aseptic operations.

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**OBSERVATION 3**
An adequate number of batches of each drug product are not tested to determine an appropriate expiration date.

Specifically:
1. Your drug product stability program for commercial drug products labeled with a 120-Day beyond use date (BUD) does not include data from direct testing of those products produced in your facility. To date you have not placed any drug products/lots produced in your facility on a stability testing program. Your stability program and current 120-day BUD for all drug products is based on data derived from testing of stability products/lots produced for this purpose in other facilities.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Edmund F Mrak, Investigator<br>Samir C Gala, Investigator<br>Jay B Shah, Investigator | X Edmund F Mrak Investigator Signed By: Edmund F. Mrak Jr -S Date Signed: 06-08-2022 11:38:28 | 6/8/2022 |

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael J. Moore, Senior Director Compounding Operations

| FIRM NAME | STREET ADDRESS |
|---|---|
| Hikma Injectables USA Inc | 36 Stults Rd |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Dayton, NJ 08810-1540 | Outsourcing Facility |

2. Your drug product stability program for commercial drug products labeled with a 120-Day beyond use date (BUD) does not include testing of container closure integrity at or beyond the labeled BUD. For example: your Report# 2021-038RA1, Compounding Development and Stability Report for 50µg/mL Fentanyl Citrate Injection (PF) for the Dayton Outsourcing Facility does not include container closure integrity testing results for a timepoint at or beyond the labeled 120-day BUD.

***DATES OF INSPECTION**
5/23/2022(Mon), 5/24/2022(Tue), 5/25/2022(Wed), 5/26/2022(Thu), 5/27/2022(Fri), 6/08/2022(Wed)

X Samir C Gala
Investigator
Signed By: 2002953778
Date Signed: 06-08-2022 11:59:15

X Jay B Shah
Investigator
Signed By: 2003178113
Date Signed: 06-08-2022 11:59:53

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Edmund F Mrak, Investigator<br>Samir C Gala, Investigator<br>Jay B Shah, Investigator<br>X Edmund F Mrak Investigator Signed By: Edmund F Mrak.3 Date Signed: 06-08-2022 11:36:28 | 6/8/2022 |

VIA E-MAIL

10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054
(973) 331-4900 Fax: (973) 331-4969
ORAPHARM1_RESPONSES@fda.hhs.gov

June 28, 2022

**Re: Hikma Injectables USA Inc. (Hikma 503B) response to the FDA 483 Observation related to the Outsourcing facility Inspection from May 23, 2022 to June 8, 2022**

Dear Mr. Mrak,

We write in response to the FDA 483 observations issued on June 8, 2022, which followed FDA's inspection of the Hikma Injectables USA Inc. compounding outsourcing facility located at 36 Stults Road, Dayton NJ 08810.

The detailed responses to the observations and comments that FDA investigators raised in the FDA 483 form are set forth below. If the agency has any questions, please do not hesitate to contact us. If there are additional explanations or documents the agency needs in order to evaluate our response, we will provide them as quickly as possible.

Hikma 503B values its partnership with FDA and takes great pride in providing high quality, safe, effective, and needed compounded sterile products to the U.S. market. Hikma 503B knows it must be ever vigilant of quality, however, especially as its business evolves and grows. The responses below demonstrate our commitment to quality and compliance and address any and all concerns the agency has about our operations.

## I. Company Overview

Hikma Injectables USA Inc. (dba Hikma 503B) is based in Dayton, New Jersey, where it has been in commercial production since December 2021 and has been registered with the FDA as an outsourcing facility since September 2021. At its current facility, it makes single use syringes and IV bag sterile injectable drugs working on one shift 5 days a week. It employs just under 50 people, including approximately 29 in manufacturing operations and approximately 20 in the facility's Quality Organization.

Hikma Pharmaceuticals PLC is the parent company of Hikma Injectables USA Inc. Through various subsidiaries, Hikma Pharmaceuticals operates drug-manufacturing facilities in the United States, Europe, the Middle East, and North Africa. The high-quality drugs made in these facilities are delivered to markets around the world.

## II. Manufacturing Operations

Hikma Injectables 503B Dayton facility is a dedicated, purpose-built facility designed to meet FDA requirements, adding segregation and automation as a differentiator within the industry. Hikma's expertise, talent, and engrained commitment to quality ensure our 503B business meets cGMP (Current Good Manufacturing Practice) standards.

Hikma Injectables 503B Dayton sterile compounding facility is dedicated to repackaging sterile-to-sterile injectables into ready-to-administer syringes or IV bags for use in hospitals. The same Quality that has underpinned the manufacture and distribution of hundreds of millions of vials to US hospitals is the basis of Hikma's 503B business.

**III. Summary of Corrective Actions**

| Observations | | Documentation | Corrective Action |
|---|---|---|---|
| 1 | 1a, 1c | SOPDTN15162 (**Exhibit#1**)<br>WIDTN15011 (**Exhibit#2**)<br>Training on Continuous Monitoring (**Exhibit#3**)<br>CAPA-0027/22 (**Exhibit#23**)<br>MemoDTN15035 (**Exhibit#4**)<br>VLDRepDTN15005 (**Exhibit#11**) | **SOPDTN15162** was revised for the need to perform continuous particle monitoring during the entire operation process and to add the exact location where the isokinetic probe will be placed inside the hood per process type.<br>**WIDTN15011** was revised to instruct the personnel on how to set the particle counter to perform continuous particle monitoring.<br>Personnel in operations were trained with **live training** in both procedures.<br>Dynamic smoke studies were repeated in all hoods currently qualified and in use for commercial compounding (CAPA00027/22 - hoods located in suites 142-3 to 142-12) and syringe fillers covering particle counter continuous functioning in the different processes per hood. A summary was written (**MemoDTN15035**) to describe the activities.<br>Moreover, an engineering study was performed to confirms that the non-viable particle counter orientation did not have an impact on data collected during routine operations inside the ISO 5 environment (**VLDRepDTN15005**). The evaluation performed assures with 95% confidence level, that there is no statistically significant difference between the particle counts collected by a horizontally or vertically oriented isokinetic probe demonstrating the commercial batches compounded in ISO 5 are not negatively impacted. |

| Observations | | Documentation | Corrective Action |
|---|---|---|---|
| | 1 b | SOPDTN15162 (**Exhibit#1**)<br>WIDTN15011 (**Exhibit#2**)<br>Training on Particle Counter Orientation (**Exhibit#3**)<br>CAPA-0027/22 (**Exhibit#23**)<br>MemoDTN15035 (**Exhibit#4**) | **SOPDTN15162** was revised to clarify the positioning of the isokinetic probe directed into the air flow direction and to add the exact location where the isokinetic probe will be placed inside the hood per process type.<br>**Instructor Led training** was given to personnel in operations on the procedure detailed in **WIDTN15011**.<br>Dynamic smoke studies were repeated on all hoods currently qualified and in use for commercial compounding (CAPA0027/22 - hoods located in suites 142-3 to 142-12) and syringe fillers covering particle counter continuous functioning in the different processes per hood. A summary was written (**MemoDTN15035**) to describe the activities. |
| | 2 | MMFDocDTN15011 (**Exhibit#20**)<br>SOPDTN15121 (**Exhibit#5**)<br>Training on Settle Plate Placement (**Exhibit#6**)<br>CAPA-0027/22 (**Exhibit#23**)<br>MemoDTN15035 (**Exhibit#4**) | Design of an Environmental Monitoring (EM) program (**MMFDocDTN15011**) **Exhibit #20** was updated to document the rationale behind the criticality of the routine locations performed in ISO 5. New settling locations were added to ISO 5 hoods for pooling and final container filling to monitor the activities occurring when the manual aseptic processing occurs. Consequently, **SOPDTN15121** was revised to add the new locations for routine monitoring with the specific instruction on where to locate the plates, per process.<br>**Instructor Led training** was given to personnel in operations, on the procedure **SOPDTN15121**.<br>Dynamic smoke studies were repeated on all hoods currently qualified and in use for commercial compounding (CAPA00027/22 - hoods located in suites 142-3 to 142-12) and syringe fillers covering particle counter continuous functioning in the different processes per hood. A summary was written (**MemoDTN15035**) to describe the activities. |

| Observations | | Documentation | Corrective Action |
|---|---|---|---|
| 2 | - | CAPA-0027/22 (**Exhibit#23**)<br>MemoDTN15035 (**Exhibit#4**)<br>MMFDocDTN15033 (**Exhibit#7**)<br>MMFDocDTN15039 (**Exhibit#8**)<br>ReportDTN15001 (**Exhibit#9**) | **CAPA-0027/22** was initiated to execute dynamic smoke studies on all hoods with all processes and include demonstrating the doors open and close during the process.<br>Dynamic smoke studies were re-performed to all hoods currently qualified and in use for commercial compounding (hoods located in suite 142-3 to 142-12) where aseptic manual operations were simulated. During this test, doors of the suites were opened/closed and videos were recorded to provide evidence that does not impact nor disrupt the air flow direction in the ISO 5 areas. A summary was written (**MemoDTN15035**) to describe the activities.<br>An equivalence study of the laminar flow hoods was done (**MMFDocDTN15033**) for performance showing that hoods are equivalent and the risk of producing different results during aseptic operations is low. Moreover, an equivalence study of the aseptic operations simulated during smoke tests (pooling, subassembly, final container filling) has been done (**MMFDocDTN15039**) where it was demonstrated that the manual aseptic interventions employed are equivalent for pooling and final container filling and subassembling process type (supported by the Media Fill Program Design Rational **ReportDTN15001**) and that the smoke tests performed to cover one process, can be extrapolated to cover the other processes. |
| 3 | - | MMFDocDTN15037 (**Exhibit#12**) | A Risk Assessment Report was completed detailing the Factors Affecting the BUD Determination for the Products Manufacturing at Hikma Injectables USA Inc. |

| Observations | | Documentation | Corrective Action |
|---|---|---|---|
| | 2 | TestProtDTN15007 (Exhibit#13)<br>TRDTN15016 (Exhibit#14)<br>TestProtDTN15008 (Exhibit#15)<br>SOPDTN15283 (Exhibit#16)<br>SOPDTN15125 (Exhibit#17) | A Protocol (**TestProtDTN15007**) was created to perform CCIT on products that were used in stability studies. A Report (**TRDTN15016**) was completed detailing the results from the CCIT testing in Protocol TestProtDTN15007.<br>A second Protocol (**TestProDTN15008**) was created to perform CCIT on products that were compounded at the Dayton facility and have come to or are about to come to the BUD.<br>The BUD/Stability SOP from the Cherry Hill facility was split to create the full stability program SOP detailing out initial and annual stability, including CCIT.<br>SOPDTN15125 on Visual Inspection was provided to support release testing leak tests. |

| Comments | Documentation | Corrective Action |
|---|---|---|
| 1 | USPVSOP 001<br>(Exhibit#18) | **USPVSOP 001** was revised to include 15 day requirement to report |
| **2** | USPVSOP 001<br>(Exhibit#18) | **USPVSOP 001** was revised to include directions for using the online portal |
| **3** | CAPA-0032/22<br>(Exhibit#24)<br>FPDTN15252 (checklist)<br>(Exhibit#19) | **CAPA-0032/22** initiated to create proofs to incorporate "This is a" in the statement "Compounded Drug" to include the full statement "This is a Compounded Drug" |

## IV. Response to Observation 1

**Observation 1 of the June 8, 2022, FDA 483 states as follows:**

***Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.***

***Specifically:***

1. ***Your airborne particulate monitoring program for aseptic operations is not designed and conducted to provide meaningful data to support the quality of your drug products intended to be sterile. You do not monitor airborne particulates to ISO 5 air classification throughout aseptic operations and the orientation of the particulate counter isokinetic probe is not directed into the flow of air during monitoring. For example:***

    a. ***On 05/24/2022 during the aseptic filling of Ketamine HCl 50 mg per mL Injection, NDC 63037-137-25, lot No.: 221430001D in cleanroom 142-6 within ISO 5 Horizontal Laminar Flow Hood No.: GE-CMP-ELH026, we observed that airborne particulate monitoring was performed only one at a time for approximately one minute during the operation. You do not provide scientific justification for the frequency and duration of airborne particulate monitoring performed during aseptic operations in the critical zone of the ISO 5 Horizontal Flow Hood.***

    c. ***Requirements written in your procedure SOPDTN15162, Routine Non-Viable Particle Count Procedure, Effective 02/28/2022, specify an airborne particulate monitoring frequency of only one time for one minute during each aseptic compounding and filling operation to include pooling, subassembly, and syringe or IV Bag filling. You do not provide scientific justification for this frequency and duration of airborne particulate monitoring performed during aseptic operations in the critical zone of the ISO 5 Horizontal laminar Flow Hood.***

**Hikma's Response to Observations 1, *1a and 1c***

For organizational purposes, Observation 1a and 1c have been grouped together, as one speaks to an observed activity and the other speaks to the written procedure on the observed activity.

Hikma Injectables USA Inc. acknowledges that the duration of non-viable particle monitoring is not performed throughout aseptic operations (pooling, sub-assembly and filling), as it is currently performed one time per laminar flow hood for 1 minute duration drawing in 75 liter samples. Therefore, Hikma Injectables USA Inc. evaluated the current process and has updated the procedure to allow for continuous monitoring throughout aseptic operations. To illustrate the corrective measures that were completed, Hikma has made the following procedure updates:

- SOPDTN15162 "*Routine Non-Viable Particle Count Procedure*" has been revised to reflect the continuous NVP monitoring throughout each of our aseptic processes in the ISO 5 classified areas – **See Exhibit #1.**

- WIDTN15011 "*Non-Viable Particle Monitoring Using an Airborne Particle Counter*" has been revised to provide instructions on how to program the portable counter to perform continuous particle monitoring throughout each of our aseptic processes in the ISO 5 classified areas – See **Exhibit #2.**

  Live, instructor-led training has been provided for technicians who will operate the equipment, as well as technicians who will support the compounding operations to understand the requirements for each laminar airflow hood and compounding suite – See **Exhibit #3**

- The newly executed smoke studies for the hoods being used in commercial activities included the placement of the NVP monitoring equipment for the entirety of each aseptic process – See **Exhibit #4, Exhibit #21** and **Exhibit#22.**

***b. On 05/24/2022 during aseptic filling of Ketamine HCl 50 mg per mL Injection, NDC 63037-137-25, Lot No.: 221430001D in cleanroom 142-6 within ISO 5 horizontal Laminar Flow Hood No.: GE-CMP-ELH026, we observed that the orientation of the particle counter isokinetic probe was not directed into the flow of air during monitoring. The particle counter isokinetic probe was positioned nearly vertically in the horizontal laminar flow hood where the airflow is expected to be horizontal as delivered from the HEPA filter in the back of the hood. You do not provide scientific justification for the observed orientation of the particle counter isokinetic probe.***

**Hikma's Response to Observation 1, *1b***

Hikma Injectables USA Inc. acknowledges that the orientation of the isokinetic probe of the NVP monitoring equipment throughout aseptic operations (pooling, sub-assembly and filling), as it was observed to be nearly vertical in the horizontal laminar airflow hood. Therefore, Hikma Injectables USA Inc. evaluated the current process and has updated the procedures to define an optimized orientation of the isokinetic probe to be directed toward the airflow. To illustrate the corrective measures that were completed, Hikma has made the following updates:

- SOPDTN15162 "*Routine Non-Viable Particle Count Procedure*" has been revised to reflect the orientation of the isokinetic probe of the NVP monitoring equipment throughout each of our aseptic processes in the ISO 5 classified areas – See **Exhibit #1**

- WIDTN15011 "*Non-Viable Particle Monitoring Using an Airborne Particle Counter*" has been revised to provide clarification of the verbiage as well as a picture of the correct orientation of the isokinetic probe of the NVP monitoring equipment for continuous monitoring throughout each of our aseptic processes in the ISO 5 classified areas – See **Exhibit #2.**

- Live, instructor-led training has been provided for technicians who will operate the equipment, as well as technicians who will support the compounding operations to understand the requirements for each laminar airflow hood and compounding suite – See **Exhibit #3**

- The newly executed smoke studies included the placement of the NVP monitoring equipment with the correct orientation of the isokinetic probe of the NVP monitoring equipment for the entirety of each aseptic process – See **Exhibit #4, Exhibit #21** and **Exhibit#22.**

***2. On 05/24/2022 during the aseptic filling of Ketamine HCl 50 mg per mL Injection, NDC 63037-137-25, Lot No.: 221430001D in cleanroom 142-6 within ISO 5 Horizontal Laminar Flow hood No.: GE-CMP-ELH026, we observed that the passive airborne viable monitoring (settling plate) location was adjacent to the HEPA filter face in the back of the hood. You do not provide scientific justification for the observed monitoring location. Your procedure SOPDTN15121, Microbiological Environmental Monitoring of Compounding Department, Effective 02/28/2022, describes the passive airborne viable monitoring (settling plate) location as "Inside LFH, back of the workbench".***

**Hikma's Response to Observation 1, *2***

Hikma Injectables USA Inc. acknowledges the placement of the passive airborne viable monitoring (settle plate) inside the ISO 5 hood was adjacent to the HEPA filter for the aseptic operations (pooling, sub-assembly and filling). The current location is around 6 inches away from the HEPA filter close to where the aseptic operations occur (as presented in the picture below), in a hood with 22 inches in depth.

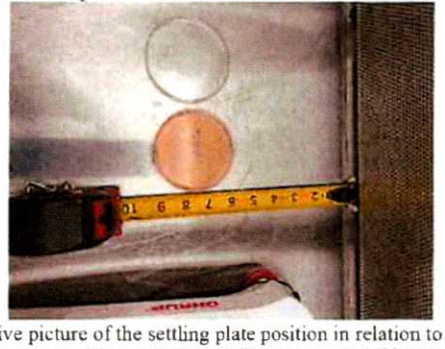


**Figure 1:** Illustrative picture of the settling plate position in relation to the HEPA surface
(*extracted from MMFDocDTN15036 – **Exhibit#10***)

The location of the passive airborne viable monitoring (settle plate) was chosen to be close the aseptic operations, and due to the limited space, the location was chosen to be in its current position. Hikma Injectables USA Inc. evaluated the current process and has added a second location for a passive airborne viable monitoring (settle plate) to pooling and final container filling processes to ensure passive air monitoring coverage of all critical sites inside the ISO 5 hoods (Figure 2 and 3a and 3b). For the sub-assembly process, based on the location of the critical site, only 1 plate will be used to capture the critical connection while allowing for placement of the particle counter (Figure 4).

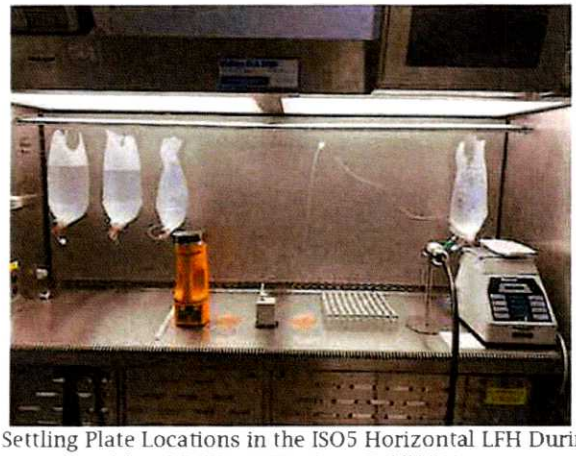


**Figure 2** - Pooling process: Settling Plate Locations in the ISO5 Horizontal LFH During Batch Processing (*extracted from MMFDocDTN15011 – **Exhibit#20***)

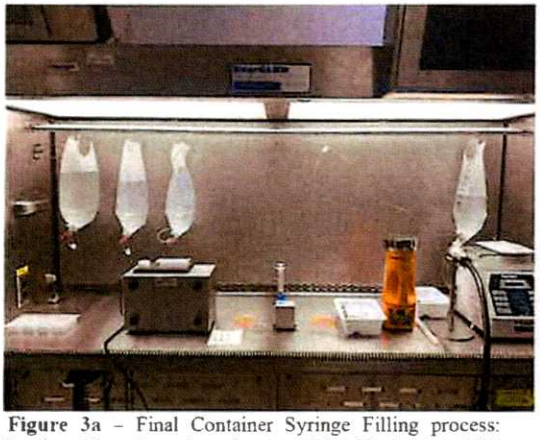


**Figure 3a** – Final Container Syringe Filling process: Settling Plate Locations in the ISO5 Horizontal LFH During Batch Processing (*extracted from MMFDocDTN15011 – **Exhibit#20***)

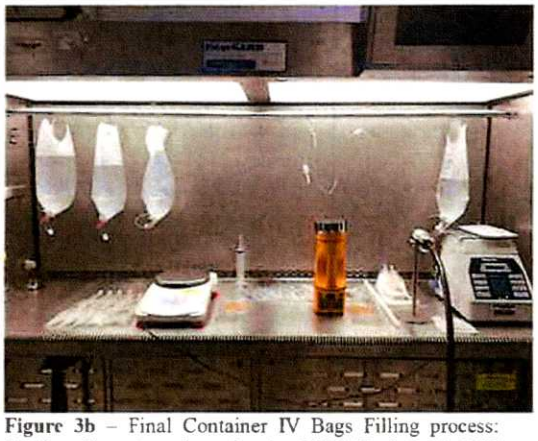


**Figure 3b** – Final Container IV Bags Filling process: Settling Plate Locations in the ISO5 Horizontal LFH During Batch Processing (*extracted from MMFDocDTN15011 – **Exhibit#20***)



**Figure 4** – Manual Sub-assembly process: Settling Plate Locations in the ISO5 Horizontal LFH During Batch Processing (*extracted from MMFDocDTN15011 – **Exhibit#20***)

Therefore, Hikma 503B has updated the procedures to include specific pictures (as above) as well as more detailed description on the location of the passive air monitoring (settle plates) depending on the process. The detailed description ensures comprehensive instructions to avoid positioning the plates too close to the HEPA filter in the ISO 5 hood. To illustrate the corrective measures that were completed, Hikma has made the following updates:

- SOPDTN15121 "*Microbiological Environmental Monitoring of Compounding Department*" has been revised to define and illustrate the location of the settling plates for each of our aseptic processes in the ISO 5 classified areas – See **Exhibit #5.**

- Live, instructor-led training has been provided for technicians who will place the settling plates, as well as technicians who will support the compounding operations to understand the settling plate requirements for each laminar airflow hood and compounding suite – See **Exhibit #6**

- The newly executed smoke studies included the placement of the settling plates for the entirety of each aseptic process – See **Exhibit #4, Exhibit #21** and **Exhibit#22..**

## V. Response to Observation 2

**Observation 2 of the June 8, 2022, FDA 483 states as follows:**

***Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.***

***Specifically:***

***You have not evaluated the airflow pattern in all your ISO 5 Horizontal Laminar Flow Hoods under dynamic conditions simulating every aseptic operation performed in each hood during sterile-to-sterile compounding and aseptic filling of your drug products intended to be sterile.***

***Inspectional evaluation of your ISO 5 area airflow pattern studies; Document No.: MMFDocDTN15033, Risk Assessment Regarding the Equivalency of the LFH through the process of dynamic smoke studies, Approved Date: 05/26/2022; and List of Commercial Batches Compounded related with hood smoke studies in dynamic, revealed that numerous products/lots were produced during the period 02/22/2022 to the present through aseptic operations performed in ISO 5 Horizontal Laminar Flow Hoods for which there was no direct dynamic airflow pattern evaluation. For example, Fentanyl Citrate 50 mcg/mL (100 mcg per 2 mL) in 0.9% Sodium Chloride Injection, NDC 63037-190-25, Lot No.: 220750002D, Expiry: 07/15/2022, was produced in cleanroom suite 142-7 and filled in ISO 5 Horizontal Laminar Flow Hood No.: GE-CMP-ELH025 which was not directly assessed in an airflow pattern study for the aseptic syringe filling operation.***

***Furthermore, your dynamic airflow pattern studies performed in ISO 5 Horizontal Laminar Flow Hoods did not consider the condition when the cleanroom suite (housing the ISO 5 Hoods) doors are opened momentarily during aseptic operations.***

**Hikma's Response to Observation 2**

Hikma Injectables USA Inc. acknowledges the dynamic smoke studies were not performed for all the ISO 5 laminar airflow hoods for all the aseptic operations (pooling, sub-assembly and filling). When considering the rationale for the execution of dynamic smoke studies, Hikma Injectables USA Inc. decided not to perform the dynamic studies for all processes per ISO5 hoods simulating all interventions and utilized a bracketing approach for the following reasons:

- Hikma 503B performed static smoke studies for all ISO5 hoods and demonstrated equivalency of performance as per **Exhibit #7** (MMFDocDTN15033 "*Risk Assessment Regarding the Equivalency of the LFH through the process of dynamic smoke studies*");

- The interventions performed on the hoods are, as per **Exhibit #8** (MMFDocDTN15039 "*Report on the Equivalence of the Aseptic Operations Simulated During Smoke Test*") considered equivalent as per the equivalency intervention list (ReportDTN15001 "*Media Fill Program Design Rational – Hikma Injectables USA*" – **Exhibit#9**)

- The set-up of the compounding processes in the hood for those interventions are considered equivalent. As part of the initial dynamic smoke studies, Hikma 503B demonstrated dynamic smoke studies for at least one of aseptic processes and/or interventions in each hood as per the Risk Assessment for the aseptic operations equivalency (**exhibit#8**) to conclude that these interventions will not affect the direction of the air and does not cause turbulence that might affect the sterility assurance of the products compounded.

As a corrective measure, CAPA-0027/22 (**Exhibit#23**) was initiated to perform dynamic smoke studies for all compounding sub-processes in all of the ISO 5 laminar airflow hoods to demonstrate the effectiveness of the bracketing approach Hikma used for the initial dynamic smoke studies as part of the room qualification. Hikma immediately executed smoke studies starting with the qualified rooms that will be used in production. Smoke studies were performed from 23May2022 through 27May2022 incorporating the placement of the isokinetic probe facing the HEPA filter for the entirety of the processes. Additionally, the smoke studies included the new settle plate locations which incorporated the additional plate per process, where sufficient room and critical locations dictated. CAPA-0027/22 has been extended to include the remaining rooms incorporating a new process utilizing and automatic compounding device (ACD) for the sub-assembly process.

Although the ISO 5 aseptic compounding suite doors were opened and closed during the initial dynamic smoke studies, Hikma 503B did not include the opening and closing of the compounding suite doors as a measured parameter and did not record the activity. As an additional corrective measure, Hikma 503B included recording the compounding suite door activity as part of the newly executed smoke studies. A separate recording of the doors of the compounding suites was incorporated into the process and saved to the files to demonstrate the frequent opening and closing of the doors to the compounding suites (**Exhibit#22**). See **Exhibit #4** for a summary of the scope of the dynamic smoke studies. Hikma has included **Exhibits #21E1.1** through **Exhibits #21E2.5** as an example for suite 142-7, to demonstrate the newly executed smoke studies as well as the open door effect to the compounding process, seen in

**Exhibits #22A** through **Exhibit #22F. Exhibit#21** summarizes all the smoke studies performed per hood presenting the individual records that demonstrate that smoke tests have been performed for all the hoods covering all the manual aseptic processes, environmental monitoring and doors open/close activities.

**Impact on the marketed compounded products in response to observation 1 and 2**

Hikma recognizes the FDA's concerns regarding the environmental monitoring program combined with the lack of smoke studies performed for every aseptic process in every laminar airflow hood. Based on the environmental monitoring and smoke study observations noted in the FDA form 483, the products that were produced in the Hikma 503B Dayton facility were reassessed to evaluate the impact on their quality. A risk assessment (MMFDocDTN15036, "*Risk Assessment Report on the Released Batches at Hikma Injectables USA Inc*") was made using the Failure Modes Effect Analysis Methodology ("FMEA") and has been submitted as **Exhibit #10**. Table 1 below summarizes the risk assessment performed to the commercial released products.

Additionally, a risk assessment report for hood equivalence **(Exhibit #7)** as well as a comparison of the aseptic operations simulated during smoke test **(Exhibit #8)** has been performed. These reports allow to conclude the hoods are equivalent in terms of performance and the risk of producing different results during aseptic operations is low. Additionally, the reports illustrate that the manual aseptic interventions employed are equivalent for pooling, the subassembly process, and final container filling (supported by the "*Media Fill Program Design Rational*" ReportDTN15001 - **Exhibit #9**) Lastly, the reports indicate the smoke tests performed to cover one process in a certain hood can be extrapolated to cover the other processes in the same hood.

Furthermore, an engineering study comparing the orientation of the isokinetic probes was executed to determine if there was a significant difference in a vertical and horizontal positioning of the isokinetic probe. The results of this study have been incorporated into the risk assessment for release of products. The engineering study (VLDRepDTN15005 "*Report for Study of the Orientation of the Non-Viable Particle Counter Isokinetic Probes in Horizontal LFH*") has been included as **Exhibit #11.**

Moreover, the engineering study performed confirms that the non-viable particle counter orientation did not have an impact on data collected during dynamic conditions inside the ISO 5 environment. The evaluation performed assures with 95% confidence level, that there is no statistically significant difference between the particle counts collected by a horizontally or vertically oriented isokinetic probe demonstrating the commercial batches compounded in ISO 5 are not negatively impacted.

The recovery rates from the period of 18th of February and 26th of May were trended. During this period, 523 active air samples were taken (zero recoveries) , 620 passive air samples were measured (1 CFU recovered on one sample) , and 547 contact surfaces were sampled (zero recoveries) making a total of 1690 samples taken with zero recoveries, except one passive air recovered. This supports that the controls in place are effective in creating a controlled aseptic environment to support sterile filling operation (for more details please refer to table 1 and table 2 page 12 of **Exhibit # 10).**

Based on the data above, the risk assessment, and the engineering study that was performed **(Exhibit#10)**, it could be concluded that all current environmental engineering controls that are in place indicates that sterility assurance of the products produced at Hikma Injectables USA Inc. was not compromised.

**Table 1 – Summary of the Risk Assessment on the Release of Commercial Batches compounded at Hikma Dayton 503B.**

| Risk Assessment | | Risk Control | |
|---|---|---|---|
| | | Risk Reduction Strategy | |
| **Factors Affecting the Sterility Assurance of a drug product** | **Failure Mode (Risk Identification)** | **Hikma Dayton 503B** | **Impact on SAL** |
| Building and Facilities / Premises / Personnel and Materials Flows | Absence of adequate room design will generate contamination with particles and loss of differential pressure, resulting on transferring contamination inside the critical areas and hence compromise the sterility assurance of the products | As per design, facility has implemented the premises and equipment, personnel and material flow adequate to the compounding of manual aseptic drugs. Quality systems are in place to assure that premises and processes are maintained in a state of control during the lifecycle of the products. | No impact |
| Equipment, Components and Container / Closure | Non qualified equipment are not reliable; Materials not meeting the requirements of sterility and not being disinfected prior to enter in the classified areas / critical areas compromise the Sterility Assurance and hence products will be deemed nonsterile | Equipment engaged in GxP related activities are qualified as and any change will be evaluated through the implemented Quality Systems in place. All materials / components used in compounding activities are bought sterile and procedures are in place to control those materials since arrival until final used in the compounding activities. | No impact |
| Process Time Limitations | Absence of process time limitations for personnel and materials/components inside the classified / critical areas compromise Sterility Assurance and hence products will be deemed nonsterile | Manual Aseptic Processes (MAP) are dependent on personnel and are critical. Process time limitations was determined for the critical processes such as Operator Fatigue and clean hold times of materials / components. These times were validated through Media Fill and the quality systems implemented assures that these times are verified for each batch being released. | No Impact |
| Manual Aseptic Processes (MAP) | MAP is not validated compromise Sterility Assurance hence products will be deemed nonsterile | MAP is performed in qualified classified areas using equipment that went through a thorough qualification process. All material / components in direct contact with the product are bought sterile and are released by QA prior to use. Configuration of equipment inside the critical area (hood ISO 5) is defined and it was challenge through Media Fill and dynamic smoke tests. No impact was seen on the sterility assurance of the operations. | No Impact |
| Finish Product tested for Sterility and Endotoxin content | Product not tested for sterility nor endotoxin content compromise the Sterility Assurance and hence products will be deemed nonsterile | Release testing is performed to every batch as per product approved specification. Bacterial endotoxin and sterility following methods described in Sterility Test <71> and Bacterial Endotoxins Test <85>, are applied to each compounded batch before the release. Suitability of the methods was verified for the compounded sterile preparations produced in Hikma Injectables USA Inc. Each batch is released by Quality after thorough review of the batch documentation. | No Impact |

## VI. Response to Observation 3

**Observation 3 of the June 9, 2022, FDA 483 states as follows:**

***An adequate number of batches of each drug product are not tested to determine an appropriate expiration date.***

***Specifically:***

1. ***Your drug product stability program for commercial drug products labeled with a 120-Day beyond use date (BUD) does not include data from direct testing of those products produced in your facility. To date you have not placed any drug products/lots produced in your facility on a stability testing program. Your stability program and current 120-day BUD for all drug products is based on data derived from testing of stability products/lots produced for this purpose in other facilities.***

A stability program was developed for each compounded product to be produced at Hikma Injectables USA Inc., by Hikma's Pharmaceutical Development teams that are located in Hikma Pharmaceuticals Injectable facility, located in United States, Cherry Hill (south west of Dayton) and in Hikma Farmacêutica (Portugal), S.A located in Sintra, Portugal (EC country) sister companies, to establish the period during which the quality and safety characteristics of compounded product are ensured (BUD) and at which storage conditions.

The premises employed in the stability program carried out by each distinct Development team, hence in distinct facilities, followed the exact same approach and strategy, which means:

- Mimic the same conditions and environment as settled for the compounding of the commercial batches;
- Simulate the same compounding process steps as the ones defined for the production of the commercial compounded products;
- Use the same components and materials or equivalent to the ones that will be employed for the commercial compounded products;
- Use equivalent qualified equipment to support the activities;
- Perform testing using the same validated methods that will be afterwards used to analyze the commercial compounded product against release specification.

A Risk Assessment Report on the Factors Affecting BUD Determination for the Products Manufacturing at Hikma Injectables USA Inc. (MMFDocDTN15037) was performed (**exhibit #12**). The risk assessment concluded that the critical factors affecting BUD are the primary packaging materials, storage conditions, materials used in compounding process, filling equipment and testing methods and these critical parameters do not depend on if the study was performed in a certain physical location or not.

A summary of the risk assessment is presented in the table 2 below:

**Table 2 – Side-by side Comparison of the factors affecting BUD determination and its impact on the current process at Hikma Dayton 503B (extracted from Exhibit#12).**

| Risk Assessment | | Risk Control | | | |
|---|---|---|---|---|---|
| | | Side-by-side Comparison | | Impact on BUD Determination | Assessment |
| Factors Affecting the BUD Determination | Failure Mode (Risk Identification) | Hikma sites | Hikma Dayton 503B | | |
| Primary Packaging components in which compounded drug is stored (container closure) | Interaction with the product resulting in a product that does not meet quality attributes. | As per Table 1 (Exhibit#12) components used in Hikma sites are the same for syringes, IV Bags and capping seals. | As per Table 1 (Exhibit#12) components used in Hikma Compounding center are the same for syringes, IV Bags and capping seals. | No impact | The same components that come in direct contact with the product, hence if a study was performed in one site, it does not need to be repeated to redetermine the BUD in another site. |
| Disposable components that come in direct contact with the compounded product | Interaction with the components that might affect the physiochemical properties of the compounded drug resulting in a product that does not meet quality attributes. | As per Table 3 (Exhibit#12) components used in Hikma sites (tubes, intermediate bags and needles) are made of the same material and are equivalent to the ones used in Hikma Compounding Center. | As per Table 3 (Exhibit#12) components used in Hikma Compounding Center (tubes, intermediate bags and needles) are made of the same material and are equivalent to the ones used in Hikma\ Injectables, USA. | No impact | Components used in the compounding of the stability lots were from the same type of the ones used in the commercial batches; there is no impact of doing the studies in different Hikma sites. |
| Storage conditions | Do not store compounded drug as per stated in ICH to evaluate the effect on the storage conditions on the physiochemical properties of the compounded drug might result in a product not meeting quality attributes. | As per Table 4 (Exhibit#12) long term conditions were applied to the compounded products having in consideration the type of container closure: 25°C ± 2°C / 60% ±5%RH 25°C ± 2°C / 40% ±5%RH* | N/A | No Impact | As per ICH the site and location where the storage conditions are taken place does not have an impact in the quality of the compounded drugs, as they met the defined criteria established in the guidance. |
| Filling process, capping and filling equipment | Filling equipment might affect the physiochemical properties of the drug resulting in a product that does not meet quality attributes. | There is no filling machines involved other than peristaltic pumps to push the product into the components. | There is no filling machines involved other than peristaltic pumps to push the product into the components. | No impact | Supporting equipment used was from the same brand and model or similar. |
| Testing methods | Methods that are not robust to determine the physiochemical properties of the compounded drugs resulting in a product that does not meet quality attributes. | Analytical methods were developed and validated in Hikma Sites. | The methods validated in Hikma Sites were transferred to Hikma Compounding Center, as per approved protocols | No impact | The same method is used and technically transferred into Hikma Dayton 503B compounding Center. |

* Long term conditions for drug products packaged in semi-permeable containers

The stability studies were performed using the same components (i.e. tubes, sub-assembly bags, etc) and exact same container closure that the commercial compounded batches were filled in. The compounding process does not involve any machine that might affect the stability of the batch and only supportive equipment is used to fill in the compounded products into either IV bags or syringes (e.g. peristaltic pumps). Therefore, Hikma has demonstrated that the factors, which are container closure and storage conditions, that are affecting the BUD determination have been studied and support the BUD dating proposed.

*As a commitment, Hikma Injectables USA Inc. will be placing batches of commercial products that are compounded at Hikma Injectables USA Inc. on stability.*

2. ***Your drug product stability program for commercial drug products labeled with a 120-Day beyond use date (BUD) does not include testing of container closure integrity at or beyond the labeled BUD. For example: your Report# 2021-038RA1, Compounding development and stability report for 50 mcg/mL Fentanyl Citrate Injection (PF) for the Dayton Outsourcing Facility does not include container closure integrity results for a timepoint at or beyond the labeled 120-day BUD.***

Hikma Injectables USA Inc. acknowledges the container closure integrity tests (CCIT) performed as part of stability was not performed on aged product. Container closure studies were performed for each container represented in the product portfolio using Sterile Water for Injection. Additionally, Hikma completed sterility at the last timepoint of each stability study with no positive growth, indicating the integrity of the containers was maintained. Additionally, Hikma performed freeze-thaw studies on every stability batch. These results were all conforming, indicating all the physiochemical properties were maintained.

As for the CCIT, although the CCIT was demonstrated by sterility testing at the end of the BUD, Hikma performed CCIT leak testing on aged samples beyond the BUD dating from the stability lots as per protocol TestProtDTN15007 (**exhibit #13**) and all samples met the acceptance criteria (**exhibit #14** TRDTN15016 "*Container Closure System Integrity Study Report on post BUD Product*"). Furthermore, Hikma has developed protocol TestProtDTN15008, which defines the testing plan for products reaching their BUD from batches produced since the facility was released for commercial production (see **Exhibit #15**). This protocol will be executed between June 2022 and September 2022.

Hikma is committed to perform CCIT as well as full physiochemical, sterility and LAL testing for commercial lots as part of the annual stability program, as demonstrated in SOPDTN15283, Guidelines for Annual Stability for 503B Products (see **Exhibit #16**).

The risk assessment below (Table 3) was performed to identify the current controls in place to assure Container Closure System Integrity (CCSI) on the commercial batches.

Table 3 – CCSI risk assessment and controls in place on the manufactured batches at Hikma Dayton 503B.

| Risk Assessment | | Risk Control | | | |
|---|---|---|---|---|---|
| | | Side-by-side Comparison | | | |
| **Factors Affecting the BUD Determination** | **Failure Mode (Risk Identification)** | **Hikma sites** | **Hikma Injectables USA Inc.** | **Impact on BUD Determination** | **Assessment** |
| Container Closure System (CCS) consists of the primary packaging components; those components that are or may be in direct contact with the product (e.g. syringes, IV bags and caps used to seal the syringe); Suitable CCS adequately store and protect the contained pharmaceutical product from external harm. | Presence of leaks for a given product-package leading to fail the function of package protection to ensure that all product physiochemical and microbiological quality attributes are met through product expiry and use.<br><br>Thus, lack of integrity affects sterility assurance of the product. | 1.Container closure integrity study was performed for each container closure represented in the product portfolio, using sterile water for injection.<br>2.Completed sterility and BET studies at the last time point of each stability study with no positive growth indicates the integrity of the containers was maintained. | 1.Components used in Hikma Compounding Center are the same as used in Hikma sites stability batches, as per MMFDocDTN15039 **(exhibit#8)**;<br>2.Manual Leak check performed on each lot as part of visual inspection according to SOPDTN15125 **(exhibit#17)** and Sterility and BET performed as part of release testing. | No impact | 1. As part of Risk control, Leak tests were performed on Stability samples available at the Cherry Hill, NJ, facility. No leaks were detected. Results are discussed in TRDTN15016 **(exhibit#14)**.<br>2. For each NDC, one lot will be selected from the compounded products for commercial use produced in Hikma Injectables USA Inc, Dayton, and will undergo full physiochemical, sterility, and LAL testing.<br>3. Leak test will be included in stability program at the BUD timepoint according to TestProtDTN15008 **(exhibit#16)**. |



2801

**Response to Comments 1 and 2**

***Comment 1: Adverse Events SOP Missing the following, "Reporting Adverse events to the FDA within 15 days. Center Reference 2 CFR 310.305 C.***

**Comment 2: Adverse Events SOP Missing the following:** ***Reporting Adverse events to the FDA using online portal. Center Reference 21 CFR 310.305.***

As requested by the Agency, Hikma has revised our U.S. Pharmacovigilance SOPUSPV 001 "*Collection, Processing, and Submission of Adverse Events and Other Safety Reports*" **(Exhibit#18)**, to include additional specificity regarding adverse event reporting for 503B compounded drugs.

The Hikma U.S. Pharmacovigilance SOP covers adverse event reporting to FDA for all products marketed in the US. This is inclusive of New Drug Applications (NDA), Abbreviated New Drug Applications (ANDA) Over-the-counter (OTC) products and 503B Compounded Drugs (Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act).

Please note the more significant revisions and updates to the sections below:

- References Section
- Definitions Section
- Table 2 within the SOP defining timelines

References: Originally this SOP include referenced to 21 CFR 310.305 as this is the governing regulation for adverse event reporting of 503B compounded drugs. To strengthen the reference section of this SOP regarding 503B compounded drugs, we have added the following additional references:

- Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act dated October 2015
- Guidance or Industry - Providing Submissions in Electronic Format — Post marketing Safety Reports dated April 2022

Reference to the guidance "Providing Submissions in Electronic Format — Post marketing Safety Reports dated April 2022" is included as this is the Agency's most current process for the electronic submission of post marketing safety reports. The Agency states that this guidance document is applicable to human drugs compounded under section 503B of the Federal Food, Drug, and Cosmetic Act.

3. Definitions: This section was updated as follows to add a specific definition for 503B Individual Case safety report (ICSR) following

3.25 503B Individual Case safety report (ICSR)
A description of an adverse drug experience related to an individual patient or subject, formatted for electronic submission to the Agency in xml format via the US FDA Adverse Event Reporting System (FAERS) via the Electronic Submissions Gateway) (ESG) [synonym: ADE case or cases]. All 503B ICSRs will be processed as 15-day reports.

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503B

As recommended in the guidance *Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act,* Hikma will be reporting all valid Adverse Events regarding our 503B compounded drugs as expedited 15-day reports. These reports will be electronically submitted in XML format to the FDA Adverse Event Reporting System (FAERS) database through the Electronic Submissions Gateway (ESG).

**Table 2 from USPVSOP 001: Submission timelines and requirements**: The table was updated to add a row dedicated to 503B products indicating that all reports are 15-day expedited and submitted in XML to the FDA Adverse Event Reporting System (FAERS) database via ESG pursuant to the Guidance for Industry - Providing Submissions in Electronic Format — Postmarketing Safety Reports.

| Report | Timeline for initial and follow-up reporting from awareness date | Format of report and destination | Other actions |
|---|---|---|---|
| 503B reports | 15-calendar days | XML submitted to FAERS via ESG – Guidance For Industry - Providing Submissions in Electronic Format — Postmarketing Safety Reports | NA |

**Response to Comment 3**

***Comment 3: Syringe Product labels are missing a complete statement: " This is a compounded drug" - instead it says "compounded drug"***

Hikma Injectables USA (herein referred to as "Hikma") acknowledges FDA's concern regarding the primary labels on our syringe products missing the complete statement "This is a compounded drug". Instead, they are labeled as "Compounded Drug" on the primary label with the full statement, "This is a Compounded Drug" on the secondary packaging label. Hikma is committed to taking all actions necessary to ensure that our product labels comply with FDA requirements, and we are steadfast in our determination to meet our commitment. As a corrective action, Hikma has performed a full inventory of all labeled products, labels that we have in our current inventory, and labels that are in-transit to the Dayton facility that are impacted (see Table 4). Additionally, Hikma has placed a SHIP - HOLD on all in-transit syringe labels to the facility that are also impacted (see Table 4).

**Corrective Actions**

Hikma has initiated CAPA-032/22 (**Exhibit#24**) (revision of primary syringe labels to include the complete statement "This is a compounded drug") to address FDA concern. The CAPA is currently in the investigation and data gathering phase. Per CAPA-032/22 (**Exhibit#24**), Hikma will evaluate the syringe label design, procedure, form, and approval process at the Dayton facility to ensure that the quality system is fully compliant with the requirement per section 503b(a)(10)(A)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Specifically, Hikma will ensure that procedures are addressed to ensure that there is no repeat observation of the labeling concern.

In-lieu of the completed CAPA, below is a summary of key actions taken after the observation, demonstrating that Hikma is fully committed to addressing the label issues identified by FDA.

1. **Hikma label design and approval process optimized**

   We have added a checklist (Form FPDTN15252) to the label approval process to ensure all primary and secondary packaging labels are fully compliant with the requirement per 503b(a)(10)(A)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The checklist will be required to be executed by Operations, the Pharmacist-in-Charge, and Quality. See **Exhibit#19**.

2. **Labels on-hand**

   To address the concern for the labels we currently have in the facility, Hikma has committed to the agency to revise all 26 primary labels by end of Q4 2022 (December 31, 2022). In parallel to this commitment, we have ensured that all secondary labels have the full statement, "This is a compounded drug," on each labeled product.

3. **In-transit labels**

   Significantly, we have taken the immediate action of communicating to our label vendor to cease production of all syringe labels until further notice. Furthermore, we have directed the vendor not to ship any label in-transit that is missing the words "***This is a***" from the statement "***compounded drug***". As a corrective action included in CAPA-032/22 (**Exhibit#24**), for the impacted syringe labels, we will revise the label proofs to include the complete statement "This is a compounded drug".

**Product Impact Assessment**

1. An initial assessment of the label concern was performed. The assessment determined that the issue was limited to only the primary labels for syringe products. However, for those impacted products, it was confirmed that the secondary product labeling contains the complete statement "***This is a compounded drug***".
2. As of June 15, 2022, a total of 26 syringe product labels are on-hand at the Dayton facility. Five (5) of the 26 products have gone through labeling processing with the products available to the market.
3. As of June 15, 2022, a total of three (3) of the impacted products have been shipped (totaling 1,300 units).

**Interim and Long-Term Commitment**

Hikma has taken this opportunity to initiate CAPA-032/22 (**Exhibit#24**) to update all the syringe labels to fully comply with the requirement per section 503b(a)(10)(A)(i) of the FD&C Act.

**Commitment Timeline:**

1. Hikma shall proceed with distribution of those 26 syringe products. Hikma commits that by end of Q4 for the calendar year 2022, all Hikma Injectables, USA syringe labels will be revised to include the complete statement "This is a compounded drug". Any inventory of the impacted labels not yet depleted by the end of Q4 2022 shall be destroyed.
2. All new syringe labels that have not already been received into our inventory system will have the label proof design revised to include the complete statement "This is a compounded drug".

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**Table 4: Impacted syringe labels on-hand and in-transit**

| Impacted Labels On-Hand | | | | | |
|---|---|---|---|---|---|
| **Product Description** | **Product NDC** | **Label Part #** | **Missing Statement "This is a"** | **Product Labeled** | **Labeled Product Shipped** |
| ePHEDrine Sulfate 25 mg per 5 mL (5 mg/mL) in 0.9% Sodium Chloride Injection | 63037-120-25 | D-PL120-25 | Yes | No | No |
| ePHEDrine Sulfate 50 mg per 10 mL (5 mg/mL) in 0.9% Sodium Chloride Injection | 63037-121-25 | D-PL121-25 | Yes | No | No |
| ePHEDrine Sulfate 10 mg per mL in 0.9% Sodium Chloride Injection | 63037-122-25 | D-PL122-25 | Yes | No | No |
| ePHEDrine Sulfate 50 mg per 5 mL (10 mg/mL) in 0.9% Sodium Chloride Injection | 63037-123-25 | D-PL123-25 | Yes | No | No |
| glycopyrrolate 0.6 mg per 3 mL (0.2 mg/mL) Injection | 63037-124-25 | D-PL124-25 | Yes | No | No |
| glycopyrrolate 1 mg per 5 mL (0.2 mg/mL) Injection | 63037-125-25 | D-PL125-25 | Yes | No | No |
| HYDROmorphone HCl 5 mg per 25 mL (0.2 mg/mL) in 0.9% Sodium Chloride Injection | 63037-131-05 | D-PL131-05 | Yes | No | No |
| HYDROmorphone HCl 10 mg per 50 mL (0.2 mg/mL) in 0.9% Sodium Chloride Injection | 63037-132-05 | D-PL132-05 | Yes | No | No |
| HYDROmorphone HCl 25 mg per 25 mL (1 mg/mL) in 0.9% Sodium Chloride Injection | 63037-133-05 | D-PL133-05 | Yes | No | No |
| HYDROmorphone HCl 50 mg per 50 mL (1 mg/mL) in 0.9% Sodium Chloride Injection | 63037-134-05 | D-PL134-05 | Yes | No | No |
| ketamine HCl 50 mg per 5 mL (10 mg/mL) in 0.9% Sodium Chloride Injection | 63037-136-25 | D-PL136-25 | Yes | Yes | Yes |
| ketamine HCl 50 mg per mL Injection | 63037-137-25 | D-PL137-25 | Yes | Yes | Yes |
| ketamine HCl 100 mg per 2 mL (50 mg/mL) Injection | 63037-138-25 | D-PL138-25 | Yes | Yes | No |
| neostigmine Methylsulfate 5 mg per 5 mL (1 mg/mL) Injection | 63037-139-25 | D-PL139-25 | Yes | No | No |
| morphine Sulfate 25 mg per 25 mL (1 mg/mL) in 0.9% Sodium Chloride Injection | 63037-143-05 | D-PL143-05 | Yes | No | No |
| morphine Sulfate 125 mg per 25 mL (5 mg/mL) in 0.9% Sodium Chloride Injection | 63037-144-05 | D-PL144-05 | Yes | No | No |
| morphine Sulfate 2 mg per 2 mL (1 mg/mL) in 0.9% Sodium Chloride Injection | 63037-145-25 | D-PL145-25 | Yes | No | No |
| morphine Sulfate 50 mg per 50 mL (1 mg/mL) in 0.9% Sodium Chloride Injection | 63037-146-05 | D-PL146-05 | Yes | No | No |
| rocuronium Bromide 50 mg per 5 mL (10 mg/mL) Injection | 63037-155-25 | D-PL155-25 | Yes | No | No |
| rocuronium Bromide 100 mg per 10 mL (10 mg/mL) Injection | 63037-156-25 | D-PL156-25 | Yes | No | No |
| phenylephrine HCl 0.4 mg per 10 mL (40 mcg/mL) in 0.9% Sodium Chloride Injection | 63037-172-25 | D-PL172-25 | Yes | No | No |
| phenylephrine HCl 1 mg per 10 mL (100 mcg/mL) in 0.9% Sodium Chloride Injection | 63037-173-25 | D-PL173-25 | Yes | No | No |
| phenylephrine HCl 0.5 mg per 5 mL (100 mcg/mL) in 0.9% Sodium Chloride Injection | 63037-174-25 | D-PL174-25 | Yes | No | No |
| phenylephrine HCl 0.8 mg per 10 mL (80 mcg/mL) in 0.9% Sodium Chloride Injection | 63037-175-25 | D-PL175-25 | Yes | No | No |
| fentaNYL Citrate 100 mcg per 2 mL (50 mcg/mL) Injection | 63037-190-25 | D-PL190-25 | Yes | Yes | Yes |
| fentaNYL Citrate 250 mcg per 5 mL (50 mcg/mL) Injection | 63037-191-25 | D-PL191-25 | Yes | Yes | No |

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| In-Transit Labels | | | | | |
|---|---|---|---|---|---|
| **Product Description** | **Product NDC** | **Label Part #** | **Missing Statement "This is a"** | **Product Labeled** | **Labeled Product Shipped** |
| 0.9% Buffered Lidocaine HCl (buffered in 8.4% Sodium Bicarbonate) | 63037-158-25 | D-PL158-25 | Yes | No | N/A |
| 1% Buffered lidocaine HCl (buffered with 8.4% Sodium Bicarbonate) 10 mg per 1 mL Injection | 63037-159-25 | D-PL159-25 | Yes | No | N/A |
| lidocaine HCl 1% (50 mg) in 5mL Injection | 63037-162-25 | D-PL162-25 | Yes | No | N/A |
| lidocaine HCl 2% (100 mg) in 5 mL Injection | 63037-164-25 | D-PL164-25 | Yes | No | N/A |
| atropine Sulfate 0.8 mg per 2 mL (0.4 mg/mL) Injection | 63037-182-25 | D-PL182-25 | Yes | No | N/A |
| fentaNYL Citrate 2,500 mcg per 50 mL (50 mcg/mL) Injection | 63037-193-05 | D-PL193-05 | Yes | No | N/A |

We hope that our response, along with the accompanying supporting documentation, alleviates the concerns raised in the observations the FDA investigators raised in the June 8, 2022 FDA 483 and demonstrates Hikma Injectables USA Inc.'s deep commitment to quality compounding. If you have any further questions or concerns about any of the issues discussed in this response or any other issue, please do not hesitate to contact us.

Sincerely,

Cindy Mitmaro, Pharm D, MBA
Director of Quality Operations/PIC
Hikma Injectables, Dayton 503B
28 Jun 2022

CC: Natheer Masarweh
Chief Quality and Technical Affairs Officer
Injectables Division

**Attachment 1**
**List of Exhibits**

| Exhibit # | Description |
|---|---|
| 1 | SOPDTN15162 Routine NVP count procedure |
| 2 | WIDTN15011 NVP Monitoring Using Airborne Particle Counter |
| 3 | SOPDTN15162 Rev. 3.0 & WIDTN15011 Rev. 5.0 Live Training Record |
| 4 | MemoDTN15035 Summary Dynamic Smoke Studies LFH & Syringe Fillers |
| 5 | SOPDTN15121 QCM_ Microbiological EM Compounding Department |
| 6 | SOPDTN15121 Rev 3.0 Live Training Record |
| 7 | MMFDocDTN15033 RiskAssess for EquivalencyLFH for dynamic smoke studies |
| 8 | MMFDocDTN15039 Report Equivalence Aseptic Operations Simulated for Smoke Test |
| 9 | ReportDTN15001 Media Fill Program Design Rational - Hikma Injectables US |
| 10 | MMFDocDTN15036 RiskAssess Released Batches at Hikma Injectables USA Inc. |
| 11 | VLDRepDTN15005 Report Study for Orientation Particle Counter Isokinetic Probes LFH |
| 12 | MMFDocDTN15037 RiskAssess Report BUD Determination at Hikma Injectables USA Inc |
| 13 | TestProtDTN15007 CCIT Study Protocol on post BUD Product |
| 14 | TRDTN15016 CCIT Study Report on post BUD Product |
| 15 | TestProtDTN15008 CCIT Study on post BUD Commercial Product |
| 16 | SOPDTN15283 Guidelines for Annual Commercial Stability for 503B Products |
| 17 | SOPDTN15125 100% Visual Inspection Compounded Sterile Products |
| 18 | USPVSOP 001_3 AE Case Collection Processing and Submission |
| 19 | FPDTN15252 Label Specification Checklist |
| 20 | MMFDocDTN15011 Designing Viable & NV Monit Program Hikma Injectables, USA |
| 21 | List of Smoke Studies as per CAPA027-22 and forms |
| 21A | SmokesDynamicJune 2022 Suite 142-3 Hoods ELH006, ELH005 |
| 21B | SmokesDynamicJune 2022 Suite 142-4 Hoods ELH030, ELH002 |
| 21C | SmokesDynamicJune 2022 Suite 142-5 Hoods ELH029, ELH028 |
| 21D | SmokesDynamicJune 2022 Suite 142-6 Hoods ELH026, ELH007 |
| 21E | SmokesDynamicJune 2022 Suite 142-7 Hodds ELH025, ELH027 |
| ***21 E1.1*** | *142-7_GE-CMP-ELH025_13JUN2022_Pooling* |
| ***21 E1.2*** | *142-7_GE-CMP-ELH025_13JUN2022_Subassembly Part 1* |
| ***21 E1.3*** | *142-7_GE-CMP-ELH025_13JUN2022_Subassembly Part 2* |
| ***21 E1.4*** | *142-7_GE-CMP-ELH025_13JUN2022_Syringe Fill Part 1* |
| ***21 E1.5*** | *142-7_GE-CMP-ELH025_13JUN2022_Syringe Fill Part 2* |
| ***21 E2.1*** | *142-7_GE-CMP-ELH027_13JUN2022_Pooling* |
| ***21 E2.2*** | *142-7_GE-CMP-ELH027_13JUN2022_Subassembly Part 1* |
| ***21 E2.3*** | *142-7_GE-CMP-ELH027_13JUN2022_Subassembly Part 2* |
| ***21 E2.4*** | *142-7_GE-CMP-ELH027_13JUN2022_IV Bag Fill Part 1* |
| ***21 E2.5*** | *142-7_GE-CMP-ELH027_13JUN2022_IV Bag FillPart 2* |

**Attachment 1**
**List of Exhibits**
***(continuation)***

| Exhibit # | Description |
|---|---|
| **21F** | SmokesDynamicJune 2022 Suite 142-8 Hoods ELH023, ELH024 |
| **21G** | SmokesDynamicJune 2022 Suite 142-9 Hoods ELH018, ELH017 |
| **21H** | SmokesDynamicJune 2022 Suite 142-10 Hoods ELH020, ELH019 |
| **21I** | SmokesDynamicJune 2022 Suite 142-11 Hoods ELH021, ELH022 |
| **21J** | SmokesDynamicJune 2022 Suite 142-12 Hoods ELH038, ELH032 |
| **22** | Videos for Door Opening |
| **22A** | 142-7 Door View Pooling 1_13JUN2022 |
| **22B** | 142-7 Door View Pooling 2_13JUN2022 |
| **22C** | 142-7 Door View Subassembly 1_13JUN2022 |
| **22D** | 142-7 Door View Subassembly 2_13JUN2022 |
| **22E** | 142-7 Door View Filling 1_13JUN2022 |
| **22F** | 142-7 Door View Filling 2_13JUN2022 |
| **23** | CAPA-0027-22 Completion of dynamic smoke studies for all hoods / processes |
| **24** | CAPA-0032-22 Update labels for syringes |

# 10C

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440

## APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ New OUTSOURCING FACILITY
☐ Ownership Change (Provide current license number if making changes:) OUT_____
☐ 503a OR ☐ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1-3 & 4
☑ Non Publicly Traded Corporation – Pages 1-3 & 5
☐ Partnership - Pages 1-3 & 6
☐ Sole Owner – Pages 1-3 & 7

**GENERAL INFORMATION to be completed by all types of ownership**

Facility Name: PQ Pharmacy

Physical Address: 15215 Technology Drive

City: Brooksville State: FL Zip Code: 34604

Telephone: 352-477-8977 Fax: N/A

Toll Free Number: 1-888-933-9073 (Required per NAC 639.708)

E-mail: angela@pqpharmacy.com Website: www.pqpharmacy.com

Supervising Pharmacist: Hale Dimetry Nevada License #: 23496

**SERVICES PROVIDED**

Yes/No

☐ ☑ Parenteral
☑ ☐ Sterile Compounding
☐ ☑ Non Sterile Compounding
☐ ☑ Mail Service Sterile Compounding
☐ ☑ Other Services: _____

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only Date Processed: _____ Amount: 500.00 MO -

19-32297402



1.23.23

**APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY** **Page 2**

FEI Number (From FDA application): 3017374013

Please provide the name of the facility as registered with the FDA and the registration number:
PQ Pharmacy, LLC 1174799731

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
N/A

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Nate Dimetry Nevada License Number: 23496

A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: N/A

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

**APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3**

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☑

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.

Hale Dimetry

Original Signature of Person Authorized to Submit Application, no copies or stamps

Hale Dimetry

Print Name of Authorized Person

1/17/23

Date

**APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY** **Page 5**

**OWNERSHIP IS A NON PUBLICY TRADED CORPORATION**

State of Incorporation: Florida

Parent Company if any: N/A

Address: 15215 Technology Drive

City: Brooksville State: FL Zip: 34604

Telephone: 352-477-8977 Fax: N/A

Contact Person: Angela Kassay

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Hale Dimetry [redacted] Leprechaun Lane Palm Harbor, FL 34683
Name Address

b) Angela Kassay [redacted] Technology Dr. Brooksville, FL 34604
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. 1000

3) What was the price paid per share? 100

4) What date did the corporation actually receive the cash assets? 11/16/21

✓ 5) Provide a copy of the corporation's stock register evidencing the above information

**Include with the application for a non publicly traded corporation**

✓ Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

✓ List of officers and directors

PQ Pharmacy Owners

Hale Dimetry, Pharm.D.
[redacted]Leprechaun Lane
Palm Harbor, FL 34683
[redacted]
DOB: [redacted]
Ownership: 90%
Florida Pharmacist License –no disciplines
hale@pqpharmacy.com

Angela Kassay
[redacted]Technology Dr
Brooksville, FL 34604
[redacted]
DOB: [redacted]
Ownership: 10%
angela@pqpharmacy.com

Department of Health

# PQ PHARMACY

## License Number: PH33659

*Data As Of 3/22/2023*

| | |
|---|---|
| **Profession** | Pharmacy |
| **License** | PH33659 |
| **License Status** | CLEAR/ |
| **License Expiration Date** | 2/28/2025 |
| **License Original Issue Date** | 11/10/2021 |
| **Address of Record** | 15215 TECHNOLOGY DR<br>BROOKSVILLE, FL 34604 |
| **Discipline on File** | No |
| **Public Complaint** | No |

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

| | | | | | | |
|---|---|---|---|---|---|---|
| Pharmaceutics International, Inc., Cockeysville, MD | Srilatha Jaini 410-584-0001 ext=1167 | 4/28/2020 | 12/9/2022 | Not yet inspected | N/A | N/A |
| Pine Pharmaceuticals, LLC, Tonawanda, NY | Alfonse Muto 716-248-1025 | 3/9/2018 | 10/28/2022 | 5/14/2021 | Yes (https://www.fda.gov/media/152333/download) | Open[7] |
| PQ Pharmacy LLC, Brooksville, FL | Angela Kassay 352-477-8977 | 10/29/2020 | 1/10/2023 | 10/27/2022 | N/A | N/A |
| Primera Compounding, LLC, Rosenberg, TX | Basil Raad 281-202-6136 | 5/24/2021 | 12/9/2022 | Not yet inspected | N/A | N/A |
| Prisma Health Outsourcing Facility, Simpsonville, SC | Gary Jones 864-522-3800 | 12/9/2019 | 11/22/2022 | Not yet inspected | N/A | N/A |
| ProRx LLC, Exton, PA | Pardeep Gupta 484-678-8579 | 4/27/2022 | 2/9/2023 | Not yet inspected | No | N/A |
| Providence Health & Services-Washington, Tukwila, WA | Jacqueline A. Biery 425-687-4460 | 3/2/2020 | 11/2/2022 | 4/13/2022 | Yes (https://www.fda.gov/media/162962/download) | FMD-145 Letter Issued 8/16/2022 |
| Qualgen LLC, Edmond, OK | Shaun Riney 405-551-8216 | 5/23/2014 | 11/28/2022 | 9/30/2022 | Yes (https://www.fda.gov/media/163431/download) | Open |
| QuVa Pharma, Inc., Bloomsbury, NJ | Robert Nelson 832-495-4216 | 9/15/2017 | 12/17/2022 | 10/14/2022 | Yes (https://www.fda.gov/media/163673/download) | Open[7] |
| Quva Pharma, Inc., Sugar Land, TX | Robert Nelson 832-495-4216 | 9/10/2015 | 11/23/2022 | 8/18/2022 | Yes | Open[7] |
| QuVa Pharma, Inc., Temple, TX | Travis Leeah 254-933-4429 | 12/15/2015 | 11/23/2022 | 6/16/2022 | Yes (https://www.fda.gov/media/163641/download) | FMD-145 Letter Issued 1/3/2023 |
| RC Outsourcing, LLC, Lowellville, OH | Raymond R. Carlson 330-536-8500 | 10/6/2015 | 11/30/2022 | 2/8/2019 | Yes (https://www.fda.gov/media/139531/download) | Remote Regulatory Assessment Assignment Issued 3/26/2021[8] |
| Right Value Drug Stores, LLC, dba Carie Boyd's Prescription Shop, Irving, TX | Sara Lange 817-282-9376 | 7/3/2019 | 12/2/2022 | 6/27/2022 | Yes (https://www.fda.gov/media/163333/download) | Open[7] |
| RXQ Compounding LLC, Albany, OH | Edward J. Zatta 866-355-3804 | 12/11/2019 | 11/24/2022 | Not yet inspected | N/A | N/A |
| SCA Pharmaceuticals, Little Rock, AR | Lessley Denton 877-550-5059 | 12/13/2013 | 12/19/2022 | 11/7/2019 | Yes (https://www.fda.gov/media/133949/download) | WLCO and FMD-145 Letters Issued 8/19/2021 |
| SCA Pharmaceuticals, Windsor, CT | Lessley Denton 877-550-5059 | 8/3/2017 | 12/12/2022 | 11/19/2019 | Yes (https://www.fda.gov/media/134901/download) | FMD-145 Letter Issued 10/22/2021 |
| SKNV formerly registered as Sincerus Florida, LLC, Pompano Beach, FL | Michael Morelli 800-604-5032 Ext=313 | 3/10/2016 | 12/6/2022 | 9/17/2018 | Yes (https://www.fda.gov/media/120734/download) | Remote Regulatory Assessment Assignment Issued 1/29/2021[8] |

Top ()

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

### Section 1: General Information

Pharmacy Name: PQ Pharmacy LLC

NV Pharmacy or Outsourcing facility license # (if applicable):

Physical Address: 15215 Technology DR

City: Brooksville State: FL Zip: 34604

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 352-477-8977 Toll Free # (NAC 639.708, NRS 639.23286): 888-933-9073

Fax: 877-456-4512 Contact Email: angela@pqpharmacy.com

Website: www.pqpharmacy.com

Nevada Business License # (if applicable)

Supervising/Managing Pharmacist Name (NRS 639.220): Hale Dimetry

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23496 Temporary License

Name of Person with direct knowledge of compounding procedures: Cari Smith

Email of Person with direct knowledge of compounding procedures: cari@pqpharmacy.com

Telephone of Person with direct knowledge of compounding procedures: 352-477-8977 quality department

**Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)**

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☐ Low ☐ Medium ☒ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☒ Yes ☐ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

PrenisoLONE/Moxifloxacin/Bromfenac Topical Ophthalmic
PrenisoLONE/Moxifloxacin Topical Ophthalmic
PrenisoLONE/Bromfenac Topical Ophthalmic
Cyclosporine Topical Ophthalmic
Mitomycin Bladder Irrigation
Moxifloxacin Ophthalmic Injection
Dextrose 50% Injection

4. Will you be utilizing beyond use dates in excess of USP-797? ☒ Yes ☐ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:
As a FDA registered 503b we adhere to GMP requirements. We work with FDA registered third party analytical labs to validate our formulas. Testing includes but not limited to the following: method suitability development, stability staudies, container closurea, sterility, particulate, bioburden, endotoxin, pH and assay to validate our products. Our products are tested out farther than the BUD we issue on released products.

6. What laboratory performs this additional testing?

Name: ARL Bio Pharma

Address: 840 Research Parkway STE 546

City: Oklahoma State: OK Zip: 73104

Telephone: 800-393-1595

7. What is your procedure for visual inspection of compounded sterile products?
All personnel that perform visual inspection have gone through the training program set forth by quality department. All inspectors must have a yearly eye exam on file and wear proper eye wear if required. Prior to performing visual inspection on PQ products employee must complete the visual inspection kit challenge sets for each line of products we offer. Containers of final product are also inspected for defects.

8. How often do you perform glove fingertip and medial fill testing?

Finger tip samples are taken at the end of each shift inside the hood completed under four hour period, if operation goes past the four hours operator would be finger tip tested at four hour and again at the end of operation.

9. What is your policy if an employee fails a glove fingertip or media-fill test?

Quality team will open an investigation to find the root cause. Qualirt and sterile operations supervisors may need to retrain employee, some examples are proper glove changing during sterile operation, prepping product prior to introducing into the hood. The operations supervisors, pharmacist and quality will preform observational audits

10. Describe your initial and annual training program for all personnel performing sterile compounding:

All sterile operators go through an extensive list or required task and demonstrate proper use and technique when using equipment and aseptic filling. They perform media fills to confirm proper aseptic filling. They have education and training. they also have quizzes. Some examples of training are USP 800, sterile techniques, calculations and clean room etiquette

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Non-Hazardous Cleaning:
Daily: sIPA used to open rooms (ISO 7) wiping all surfaces, to open hoods (ISO 5) Vestasyde SQ (disinfectant) is applied allowing for 10-minute contact followed by sIPA. End of shift cleaning procedure is reperformed wiping all surfaces with Vestasyde followed by sIPA
Weekly: Sporklenz (sporicidal agent) 30-minute contact time followed by sIPA is substituted for Vestasyde SQ.
Monthly: Sprokelnz (sporicidal agent) of all surfaces; ceilings (excluding HEPAs), walls, equipment, work surfaces, sink, interior/exterior of passthroughs/MAL, bins, shelving, supplies thoroughly allowing for the 30-minuete contact time then followed by sIPA.

Hazardous Cleaning:
Same procedures are followed only no vestasyde is used - sporklenz is always used.

12. Who performs the sterile compounding process at your facility?

Trained sterile operators perform sterile compounding. These sterile operators are supervised by the sterile operations pharmacist and the sterile operations shift supervisors.

13. Who is responsible and accountable for the sterile compounding process at your facility?

Sterile operations pharmacist, quality department are responsible to make sure product has been tested, inspected and labeled within gmp requirements prior to releasing any products.

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

PQ Pharmacy has done shipping validations in the winter season and the summer season. All cold ships are sent overnight shipping. These cold shipments have been validated for 48 hour period. As a precaution we ship all overnight. Room temperature items are shipped overnight and 2 day day ship. All shipments are traceable with FedEx and UPS.

**Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)**

1. What type of primary engineering controls will you be using in your facility?

We have fully compliant USP 800 sterile prep room hazard sterile compounding area. Room temps, humidity, pressure and particulate are monitored 24/7. Rooms and BSCs are re-certified every six month by a third party certifier

| | | |
|---|---|---|
| 2. Is your BSC or CACI vented 100% to the outside? | ☑ Yes | ☐ No |
| 3. Do you have a negative pressure buffer room at your facility? | ☑ Yes | ☐ No |
| 4. Will you be compounding with antineoplastic HDs or HD API? | ☑ Yes | ☐ No |
| 5. If yes, are the drugs stored in an externally ventilated, negative pressure room? | ☑ Yes | ☐ No |
| 6. Will you be utilizing a closed system transfer device? | ☑ Yes | ☐ No |

7. If yes, list the name of the device:

We use BD Phaseal and ICU medical Spiros

8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

The product label contains a "Caution Chemotherapy Drug" highlighted in yellow warning. Secondary packaging has a chemotherapy warning label and an additional product label with warning. the shipping container also is flagged as a chemotherapy drug. we include a proper handling instruction card with the orders.

9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Employees are required to do hazardous training through a third party vendor on PPE, hazardous communications and biohazard waste training. Training includes handling hazardous material, how to deactivate chemo material and proper use of workspace. what to do if there is a hazard material spill as well as location of emergency eye wash stations and spill kits. We also do additional on-site training.

**Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)**

1. List the specific high risk sterile products that your facility compounds:

Mitomycin Bladder Irrigation
Mitomycin Ophthalmic Solution
Cyclosporine Ophthalmic Emulsion

2. What sterilization methods are utilized at your facility?

All products are sterilized with a capsule double filter containg a 0.45 micron and final 0.2 micron filter. All final product containers, vials, syringes and ophthalmic dropper bottles are purchased sterile ready to use

3. Does your facility utilize biological indicators? ☒ Yes ☐ No

4. If yes, describe how they are utilized:

we use BI's in each autoclave run and dry heat BI's for dry heat oven runs for our internal supplies used in the non-sterile process of compounding.

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Angela Kassay
Name of Person who Completed the Form

Director of Operations
Title

Signature (copies or stamps not accepted)

28March2023
Date

| Board Use Only | Date Received: _____ Date Approved: _____ Approved By: _____ |
|---|---|

# *State of Florida*
## *Department of State*

I certify from the records of this office that PQ PHARMACY LLC is a limited liability company organized under the laws of the State of Florida, filed on February 12, 2020, effective February 12, 2020.

The document number of this limited liability company is L20000049845.

I further certify that said limited liability company has paid all fees due this office through December 31, 2022, that its most recent annual report was filed on January 26, 2022, and that its status is active.

*Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Eleventh day of January, 2023*




*Secretary of State*

**Tracking Number: 7731387768CU**

**To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.**

**https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication**

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| RP0617398 | 03-31-2023 | $3699 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,3N | MANUFACTURER | 02-02-2022 |

PQ PHARMACY LLC
15215 TECHNOLOGY DR
BROOKSVILLE, FL 34604

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| RP0617398 | 03-31-2023 | $3699 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
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PQ PHARMACY LLC
15215 TECHNOLOGY DR
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Form DEA-223 (9/2016)

# STATE OF FLORIDA
# DEPARTMENT OF HEALTH
# INVESTIGATIVE SERVICES
## 503b Outsourcing Inspection

www.FloridaHealth.gov

File # 27519
Insp #

| NAME | PERMIT NUMBER | DATE OF INSPECTION |
|---|---|---|
| PQ Pharmacy | 33659 | 11-8-22 to 11-9-22 |
| DOING BUSINESS AS | | |
| STREET ADDRESS: 15215 Technology Drive | TELEPHONE #: 1-888-933-9073 | EXT |
| CITY: Brooksville | COUNTY: Hernando | STATE/ZIP: FL 34604 |

**Additional Information**

**Registered Pharmacist / Intern / Tech**

| | |
|---|---|
| | |

**Basic License Data - PSD**

| | |
|---|---|
| | |

**Business Operation Hours**

| | |
|---|---|
| | |

**License Relations**

**Pharmacy Affiliate**

| | |
|---|---|
| Hale N. Dimetry | License # PS39942 |
| Meena Ragheb | License # PS59756 |
| Marissa Lee Marchetti | License # RPT42835 |
| Bayley Merila | License #RPT107281 |
| Shannon Vera | License #RPT22769 |

**Special Sterile Compounding**

| | |
|---|---|
| | License # |

### 503b - Outsourcing Inspection

**Quality - 21CFR part 211 subpart B**

| | |
|---|---|
| Firm has an Independent Quality Control Unit. | Yes |
| The QC unit has the authority and responsibility to approve or reject all components, drug product containers or closures, end process materials, packaging materials, labeling and drug products. Per SOP. | Yes |
| QC unit reviews and approves/rejects: SOP's, Batch Records (completeness and accuracy, components, API's, materials, OOS results). | Yes |
| QC unit reviews production records to assure that no errors have occurred, or if errors have occurred, that they have been fully investigated. | Yes |
| Adequate laboratory facilities for the testing and approval (or rejection) of components, drug product containers, closures, packaging materials, in-process materials, and drug products are available to the quality control unit. | Yes |
| The quality unit approves or rejects all procedures or specifications impacting the identity, strength, quality, and purity of the drug product. | Yes |
| The responsibilities and procedures applicable to the QC unit are in writing and such procedures are followed. | Yes |
| QC unit personnel are qualified through training and experience. | Yes |

# 503b Outsourcing Inspection

Insp #

File #

**Investigations**

| | |
|---|---|
| The QC Unit conducts a written and thorough investigations of any unexplained discrepancy, deviation, equipment malfunctions, and OOS (including a percentage of theoretical yield exceeding the maximum or minimum percentages established in master production and control records) or the failure of a batch or any of its components to meet any of its specifications whether or not the batch has already been distributed. | Yes |
| Investigations are conducted within time limits specified per SOP. 45 days. | Yes |
| When investigations are not conducted, the written records include the reason the investigation was not deemed to be necessary and the name of the person that made that determination. | U |
| Investigations are extended to other batches that may have been impacted by a failure or discrepancy. | U |
| Investigations include findings, conclusions and follow up.<br>*DEV2022019- OOS Potency of Prednisolone Sodium Phosphate 1%/Moxifloxacin HCl 0.5%/Bromfenac Sodium Sesquihydrate 0.09%- no indication that the lot was not released, Batch Record states batch was not released.* | No |
| Record of investigations are maintained at the establishment where the investigation occurred. | Yes |

**Personnel Qualification - 21CFR Subpart B**

| | |
|---|---|
| All personnel involved in the processing, packing, or holding of a drug product have the education, training and experience to enable the person to perform the assigned functions. | Yes |
| Facility has a written training program that describes the required training, frequency of training and process for evaluating the performance of individuals involved in compounding. | Yes |
| Facility has documentation that compounding personnel have the required skills necessary to perform their assigned functions. | Yes |
| Prior to beginning to prepare CSP's personnel have completed training and have demonstrated proficiency in the principles and hands on skills of aseptic manipulations. | Yes |
| CGMP trainers are qualified through experience and training. | Yes |
| Personnel receive ongoing periodic CGMP training by qualified trainers for the specific tasks they are authorized to perform. | Yes |
| Personnel are qualified for the number of units they can compound and the processes they perform.<br>*Mitomycin Syringes (batch of 250) and POM and PMB ophthalmic drops (batch of 999)* | Yes |
| Personnel have been periodically trained in core competencies, visual observation is conducted to confirm personnel have necessary skills (I.e., Hand hygiene and garbing, aseptic manipulations, cleaning and disinfecting).<br>*BM support production personnel unable to demonstrate proper aseptic technique-did not sanitize gloved hands with SIPA prior to reaching in from the side and removing finished droptainers containing Prednisolone/Moxifloxacin HCl/Bromfenac specifically lot PMB110722IJ.* | No |
| Personnel sampling including GFT is conducted after compounding and documented on each batch record. | Yes |
| Personnel have completed media fill simulations for all aseptic compounding processes under the most difficult and challenging conditions which include the most manipulations/units, most complex flow of material, longest time to compound and all breaks and interventions. | Yes |
| Personnel are retrained and requalified after failure of media fill, GFT or batch failures. | Yes |
| Firm has adequate written procedures for visual inspection. | Yes |
| Personnel conducting visual inspection of the final product have been qualified through training in applicable SOPs and have annual eye exams.<br>*Eye exams completed 11/9/22* | Yes |
| Personnel conducting visual inspections have been qualified for the number of units and amount of time they can inspect before taking a break. | Yes |
| Significant defect categories are identified in the SOP and personnel conducting visual inspection have demonstrated competency in identifying common defects. | Yes |
| Persons supervising the manufacture, processing, packing or holding of a drug product have the education, training, and experience to perform assigned functions in a manner to provide assurance of the safety, identity, strength, quality and purity of the drug product. | Yes |
| Employees are required to report to their supervisor any health issues that might impact the quality, safety and purity of the product. | Yes |
| Temporary employees are given the same orientations as permanent employees. | U |
| The firm has records stating the name, address, and qualification of all consultants and the type of service they provide. | U |
| Documentation of training personnel on use of equipment. | Yes |

# 503b Outsourcing Inspection

**Insp #**

**File #**

**Facilities and Equipment - 21CFR part 211 subpart C and subpart D**

| | |
|---|---|
| The facility design is suitable for compounding sterile products. | Yes |
| The facility is designed to allow adequate flow of components, drug product containers, closures, labeling, in-process materials and drug products through the building to prevent contamination. | Yes |
| The facility has the space, construction, and location to facilitate cleaning, maintenance, and proper operation.<br>*Cleanroom 2 is not currently in use, but documented cleaning noted in Instant GMP* | Yes |
| There is adequate space for the orderly placement of equipment and materials to prevent mixups between different components, containers, closures, labeling, in-process materials, or drug products and to prevent contamination. | Yes |
| Facility had adequate space to quarantine incoming components, drug product containers, closures, and labeling pending the sampling, testing or examination by the quality control unit prior to release. | Yes |
| Facility has space to hold rejected components, container, closures and labeling prior to disposition. | Yes |
| There is a separate, defined area for quarantine storage before release of drug products. | Yes |
| Compounding of hazardous drugs is clearly separated from non-hazardous drugs to prevent cross contamination. | Yes |
| Beta lactams are separated to prevent cross contamination with other drug products. | U |
| Certifications of primary and secondary engineering controls are current and are conducted under dynamic, worst-case conditions with the maximum number of personnel allowed per SOP present.<br>*Certifications: Medrep Sept 19-23,2022 not completed under dynamic conditions; Prior certification March 2022-conducted under dynamic conditions for smoke study. Medrep 11/1/2022 -conducted under dynamic conditions, but prelim report does not specify number of personnel present-this must be completed per policy every 6 months. SOP does not specify the worst-case dynamic conditions with the maximum number of personnel present.* | No |
| All HEPA filters are leak tested. | Yes |
| Visual smoke studies have been conducted under operational conditions to demonstrate laminar flow air in all primary engineering controls.<br>*2 X A2 BSCs in HD room and 3 x VLFW in manual room documented as conducted under dynamic conditions by Medrep March 2022* | Yes |
| Floors, walls and ceilings and other structures are smooth and easily cleanable. | Yes |
| Ceiling tiles are clean room grade and gasketed and sealed/clipped.<br>*No ceiling tile-smooth ceiling* | U |
| Air return vents are not blocked and are placed in a manner that allows adequate dilution of HEPA filtered air to prevent airborne contamination. | Yes |
| The control of air pressure, dust, humidity and temperature is adequate for the manufacturing, processing, storage or testing of drug products.<br>*Documented in Instant GMP* | Yes |
| Pressure gauges that monitor pressure differentials are calibrated. | Yes |
| The facility is maintained in a clean and sanitary condition. | Yes |
| The facility has written procedures that describe in sufficient detail the cleaning schedule, methods, equipment and materials used in cleaning the facilities. Procedures are followed. | Yes |
| The firm has an SOP for controlling rodents, birds, insects and other vermin. Pest control contracts specify which pesticides can be used. Procedures are followed and documented. | Yes |
| The facility has a procedure for rotating cleaning solutions and documents in the cleaning record.<br>*Cleaning records from Instant GMP demonstrate firm is using Vesta syde (daily designated Quat ammonium agent) and Spor klenz (sporicidal) weekly and monthly application* | Yes |
| Sporicidal agents are used. How often?<br>*Per SOP, weekly and monthly. Spor klenz reviewed in Instant GMP* | Yes |
| The facility has validated the effectiveness of the cleaning solutions.<br>*No validation for 10-minute dwell time.of Spor Klenz; or Vesta Syde; Chamberbrite for equipment. Cleaning effectiveness studies in process with Focus labs.* | No |
| All equipment has written procedures for use. | Yes |
| Written procedures and schedules are established and followed for cleaning and maintenance of equipment and utensils used in the manufacture, processing, packing, or holding of a drug product. | Yes |

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**Insp #**

**File #**

| | |
|---|---|
| Surfaces that contact components, in-process materials, or drug products are not reactive, additive, or absorptive so as to alter the safety, identity, strength, quality or purity of the drug product. | Yes |
| Ovens and autoclaves have been temperature mapped, the cycles have been validated, and are monitored with calibrated thermometers.<br>*Tuttenauer Autoclave validated at 255 for 50min, 1 hour to reach temp.on 7/21/22, Oven greater than 250 for 30 mins from August, 2022 validation* | Yes |
| Autoclaved cycles are verified with BI's. | Yes |
| Depyrogenation cycles have been validated with ECVs and demonstrates a 3-log reduction in endotoxin units.<br>*Despatch Oven LCCI-51-4 - 8/11/22 Focus labs* | Yes |
| All equipment is validated for its intended use. | Yes |
| Refrigerators and freezers are monitored with calibrated thermometers. | Yes |
| Written SOPs for changing the filters and prefilters of all engineering controls are established and followed.<br>*Reviewed certification reports* | Yes |
| Appropriate controls over computer or related systems assure the changes in master production and control records are made by authorized personnel only. | Yes |

**Environmental Monitoring - 21CFR 211 - Subpart F**

| | |
|---|---|
| Facility has an environmental monitoring program.<br>*Facility uses TSA plates with lecithin and polysorbate 80. Incubation at 30-35 for 72 hours and 20-25 for 5-7 days. Growth promotion completed by Focus labs using the same incubation processes. No SDA plates are used.* | Yes |
| Air quality is monitored regularly using volumetric air sampling to ensure the environment remains suitable for sterile compounding. | Yes |
| Settling plates are used during compounding to monitor the quality of air during compounding processes and documented in the batch records. Per SOP | Yes |
| Non-viable particle counts occur during operations in areas most at risk to exposed product, containers and closures. | Yes |
| Surface sampling is conducted after each batch prior to cleaning and documented on batch records. | Yes |
| Surface sampling is routinely conducted in all classified spaces in those locations identified to be at highest risk of contamination. | Yes |
| Surface sampling is conducted in critical areas that are in contact with products, containers or other components used in compounding. | Yes |
| Media used in environmental, and personnel monitoring has been shown to promote the growth of microorganisms and contains agents to neutralize cleaning solutions and disinfectants. | Yes |
| Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment. | Yes |
| Environmental Monitoring Data is trended to support the adequacy of clean room quality. | Yes |
| Adverse changes in the environment are investigated and promptly remediated. | Yes |
| Alert and action levels for CFU counts have been established in SOPs for the facility. | Yes |
| Air pressure differentials are continuously monitored and demonstrate that a cascading pressure differential is maintained throughout the compounding area during production of sterile compounding. Alarms and deviations are documented, investigated, and remediated. | Yes |

**Control of Components, Containers and Closures 21CFR part211 Subpart E**

| | |
|---|---|
| Facility has a quality agreement with API suppliers to ensure all APIs are manufactured in registered FDA facilities. | Yes |
| Written procedures describe with sufficient detail the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures. Procedures are followed. | Yes |
| Components and drug product containers and closures are handled and stored, at all times, in a manner to prevent contamination. | Yes |
| Bagged or boxed components of drug product containers or closures are stored off the floor and suitably spaced to permit cleaning and inspection. | Yes |

# 503b Outsourcing Inspection

Insp #

File #

| | |
|---|---|
| Components, containers and closures are stored under quarantine until they have been sampled, tested or examined and released for use by the quality control unit. Each lot of components, containers and closures is appropriately identified as to its status (quarantined, approved, or rejected). | Yes |
| Each component is tested for conformity to written specifications for identity, purity, strength and quality. Supplier analysis may be accepted provided that at least one specific identity test has been conducted by the firm and the firm has established the reliability of the supplier's analysis through validation of supplier's test results at appropriate intervals. | Yes |
| Containers and closures are tested for conformity to written specifications. A certificate of testing from the supplier is acceptable if the reliability of the suppliers' test results is established and at least a visual identification is conducted by the firm. | Yes |
| Each lot of components with potential for microbiological contamination are subjected to microbiological tests before use. | Yes |
| Components, drug product containers and closures approved for use are rotated so that the oldest approved stock is used first. Deviations from this are temporary and appropriate. | Yes |
| Drug product containers and closures are not reactive, additive, or adsorptive so as to alter the safety, identity, strength, quality or purity of the drug. | Yes |
| Firm has written specifications, methods of testing if indicated, methods of cleaning, sterilizing and depyrogenating drug product containers and closures. | Yes |
| Facility has a system in place to ensure final drug product containers, closures and stoppers are endotoxin free. Failures are investigated and documented. | Yes |
| Written procedures include material transfer from less classified air to higher classified air and include procedures to sanitize materials prior to introduction into the clean room. | Yes |
| Facility has appropriate sterile PPE. | Yes |
| Materials for cleaning the PECs are sterile. | Yes |
| Filters used for sterilization have documentation that they are compatible with the product, are pharmaceutical grade, non-pyrogenic and capable of sterilizing the intended volume.<br>*Filter study in process* | Yes |
| Written procedures identify storage times beyond which materials must be reexamined before use. | Yes |
| Release of re-tested material clearly identified for reuse. | U |

**Production - 21CFR part 211 subpart F**

| | |
|---|---|
| There are written procedures for production and process controls to assure the drug products have the identity, strength, quality, and purity they purport to possess. Procedures are followed. Deviations are recorded and justified. | Yes |
| Components removed from the original container to another are properly labeled. | Yes |
| Weighing, measuring, or sub-dividing of components is supervised. Each container of component dispensed to manufacturing is examined by a second person. | Yes |
| Each component added to the batch is verified by a second person unless added by automated equipment under 211.68. | Yes |
| Actual and theoretical yields are determined at each production phase and are verified by a second person. If yields are calculated by automated equipment, verification is done by one person. | Yes |
| Written procedures indicate how and who verifies that correct containers and packages are used for the finished product. | Yes |
| In-process specifications have been established and followed for each production phase to ensure uniformity of drug product. | Yes |
| Control procedures include disintegration time, adequacy of mixing, dissolution times and rates where appropriate. | Yes |
| Quality control unit approves or rejects in- process materials that are tested during the production process after completion of significant phases of production. | Yes |
| Time limits are established for the completion of each production phase; Deviations are justified and documented. | Yes |
| Sterilization methods are validated.<br>*In process for sterilizing filters* | Yes |
| SOP's identify hold times for depyrogenated glassware and the hold times have been validated. | Yes |
| Integrity testing is conducted on all filters used to sterilize product and is documented on the batch record. | Yes |
| Products prepared for lyophilization are maintained in ISO 5 laminar flow air throughout the production process from sterilization, filling, and transport to the lyophilizer. | U |

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| | |
|---|---|
| There are an adequate number of personnel to supervise the manufacture processing, packing, or holding of each drug product. | Yes |
| All finished products are held in quarantine until QC has completed testing and releases the batch. | Yes |
| A 100% inspection of finished sterile products for cracks, visible particles and significant defects is performed.<br>*Expectations for the challenge set are set at 80% for minor defects* | Yes |
| Firm has written procedures that define the defects to be removed from the lot and actions to take if the number of critical defects exceeds the pre-determined level. | Yes |
| Firm has a program for sampling and examination of inspected products that evaluates the effectiveness of inspection.<br>SOP indicates AQL. | Yes |

**Packaging and Labeling - 21 CFR part 211 subpart G**

| | |
|---|---|
| Written procedures describe the receipt, identification, storage, handling, examination and/or testing of labeling and packaging material. Procedures are followed. | Yes |
| Written procedures describe control procedures employed for issuance of labeling. Procedures are followed. | Yes |
| Written procedure specifies who is authorized to issue labels and strict control is exercised over labeling operations.<br>Quality. | Yes |
| Records are maintained for each shipment received of each different labeling material indicating receipt, examination/testing, and whether accepted or rejected. | Yes |
| Labels and other labeling materials for each different drug product, strength, dosage form, or quantity of contents are stored separately and properly identified.<br>Mitomycin labels received printed with information that doesn't change per batch, eye drop labels received blank. Quality dept has access only. | Yes |
| Access to label storage area is limited to authorized personnel. -Quality | Yes |
| Obsolete and outdated labels, labeling and packaging materials are destroyed. | Yes |
| Unlabeled drug filled product containers intended for future labeling are identified with drug name, strength, quantity and lot number.<br>Product label on outside of tote. | Yes |
| Written procedure specify how labels are issued, used, reconciled with production, returned when unused, and the specific steps for evaluation of any discrepancies. | Yes |
| Written procedures call for the destruction of excess labeling on which lot and control #'s have been stamped or imprinted. Shredded by quality. | Yes |
| 100% Visual inspection is conducted for correct labeling during or after completion of finishing operations for hand applied labeling. Such examination is performed by one person and independently verified by a second person. Or use of electronic equipment to conduct 100% examination.<br>*Quality Manager states that this is done by her, batch record includes documentation by Quality 'verify label check and label reconciliation'. Change request implemented at time of inspection to indicate 100% inspection for correct labeling.* | No |
| Procedures are established and followed to assure that correct labels, labeling, and packaging materials are used. | Yes |
| Procedures are designed to prevent mix-ups and cross-contamination by physical or spatial separation from operations on other products. | Yes |
| Written procedures detail examination of packaging and labeling materials for suitability and correctness and is documented on the batch record. | Yes |
| Drug labels include the statement "this is a compounded drug, the name, address and phone # of the facility. Per SOP | Yes |
| The label of the drugs contains the lot or batch #, the established name of the drug, dosage form and strength, quantity or volume, the date the drug was compounded, the expiration date, storage and handling instructions, NDC # (if available), the statement "not for resale" and "For Office Use Only," and a list of active and inactive ingredients identified by established name and the quantity or proportion of each ingredient and route of administration. Per SOP | Yes |
| The label or container contains the following: www.fda.gov/medwatch and 1-800-FDA-1088. | Yes |
| Written procedures detail how equipment is to be checked immediately prior to use for removal of any labels, labeling, and packaging material from prior print operations and is documented on the batch record. Procedures are followed. | U |

# 503b Outsourcing Inspection

Insp #

File #

**Holding and Distribution 21CFR Part 211 Subpart H**

| | |
|---|---|
| Written procedures describing warehousing of drugs include quarantine of drug product before release by QC unit, storage under appropriate temperature, relative humidity, and light. | Yes |
| Procedures for the warehousing of drugs are followed. | Yes |
| Written procedures include FIFO of product distributed and a system whereby product can be recalled. | Yes |
| The firm has conducted shipping studies to confirm that drug products can be shipped without negatively impacting the safety, identity, strength, quality and purity of the drug product. | Yes |

**Laboratory - 21 CFR part 211 subpart I**

| | |
|---|---|
| Contract labs are FDA registered.<br>*Focus, ARL.* | Yes |
| Facility has qualified their contract labs.<br>*FOCUS- visit completed but ARL qualified through questionnaire.* | No |
| Laboratory specifications, standards, sampling plans and test procedures are approved by Quality Unit; deviations from written specifications are recorded and justified. | Yes |
| All laboratory procedures are followed and documented contemporaneously. | U |
| Laboratory controls include procedures designed to assure that components, containers, closures, drug products, and in-process materials, conform to appropriate standards of identity, strength, quality and purity. | U |
| Instruments, apparatus, gauges, and recording devices are calibrated at suitable intervals in accordance with an established written program. | U |
| Stability tests are derived from reliable, meaningful and specific tests methods and justify the assigned BUD of each drug product. | Yes |
| There is a written program to assess the stability characteristics of each product. The program includes sample size and test interval, storage conditions, and testing the drug product in the same container closure system in which the product is distributed. | Yes |
| Lyophilized products have stability data for both before and after reconstitution. No plan to compound lyophilitzed products. | U |
| Facility has approved finished product specifications for all CSPs. | Yes |
| All batches of drug products have undergone appropriate laboratory testing to determine conformance to specifications. | Yes |
| Procedures describe sampling and testing plans and include method of sampling and the number of units per batch to be tested.<br>*Samples from beginning, middle and end.* | Yes |
| Acceptance criteria for sampling and testing conducted by the quality control unit are adequate to assure that batches of drug products meet appropriate specifications. | Yes |
| Drug products failing to meet established specifications or any other relevant quality control criteria are rejected. | U |
| Stability studies, microbial effectiveness testing on the preservative, container closure studies and sterility testing have been conducted to ensure the CSP continues to meet all specifications over the intended shelf life of the product.<br>*ARL HPLC Assay and studies* | Yes |
| Sterility testing for all batches is conducted using a USP 71 test or a validated alternate test that is proven equivalent or superior to the USP<71> test. | Yes |
| Sterility tests for products requiring reconstitution are conducted using preservative free diluent. | U |
| Method suitability has been conducted for all products. | Yes |
| Endotoxin testing is conducted on all batches.<br>*Endotoxin testing on Mitomycin Irrigation Solution and no Endotoxin Testing on Topical Opthalmic Drops.* | No |
| Potency is conducted on all batches. | Yes |
| Appropriate # of articles/volume is tested for sterility. | Yes |
| The accuracy, sensitivity, specificity, and reproducibility of test methods are established and documented; failures are rejected. | U |

# 503b Outsourcing Inspection

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| | |
|---|---|
| A reserve sample, representative of each lot or batch of drug product, is retained and stored under conditions consistent with product labeling and in the same container-closure system for 1 year past the BUD of the drug product<br>*Has not been 1 year past BUD at time of inspection.* | U |

**Records and Reports 21CFR Part 211 subpart J**

| | |
|---|---|
| All records associated with a batch, including records of containers, closures and labeling are retained for at least 1 year after expiration of the batch. Records related to product distributed into the state of Florida are retained 4 years. | U |
| Written records are maintained so that data can be used for evaluating, at least annually, the quality standards of each drug product. Procedures include a review of complaints, recalls, and investigations for each drug product, and include a representative number of batches, whether approved or rejected.<br>*Annual Product Review will be completed after 1 year. No complaints received at time of inspection.* | Yes |
| Records of maintenance, cleaning, sanitizing, inspection and use of major equipment are kept and show the date, time, product, and lot number of each batch produced. *Cleaning of equipment documented in Instant GMP* | Yes |
| Logs are signed or initialed and dated by persons performing and double checking the cleaning and maintenance of equipment. Entries are in chronological order. | Yes |
| All components, containers, closures, and labeling are identified on batch records and traceable to the finished product. | Yes |
| Master production and control records for each drug product are prepared and include batch size, name and strength of product, dosage form, name and weight of each ingredient, complete list of all components, statement of theoretical yield, % deviation from theoretical yield that requires an investigation, description of containers, closures and packaging materials, specimen of labels, complete manufacturing and control instructions, sampling and testing procedures, product specification, special notations and precautions to follow. | Yes |
| Master production and control records are prepared, dated and signed with a full signature by one person and independently checked, dated and signed by a second person.<br>*Updated Master Batch Record for each CSP reviewed.* | Yes |
| Batch Production and Control records are accurate and complete.<br>*Multiple batch records for PMB 1/0.5/0.09 Calculation on page 11 of 16: Total Volume made is changed, all calculations changed.*<br>*Material used in process- batch record does not include all items, manually documented. Master Batch Record has been changed-total volume compounded blank..*<br>*PMB 1/0.5/0.09 5.6ml- lot PMB102522IJ, pg15 of 16 Post Qualification count not documented.*<br>*Media Fill TSB072121MM and TSB062322SV- BR states monoject syringe, however BD syringe used, and this was not corrected.* | No |
| Batch records include documentation that each significant step was accomplished and includes date and time. | Yes |
| Major equipment is identified on the batch record. | Yes |
| The identity of each person performing, supervising, or checking each step is documented on the batch record. | Yes |
| The firm has an SOP for product release. The production batch and control records, including those for packaging and labeling, are reviewed and approved by the quality unit to determine compliance before a batch is released or distributed. | Yes |
| Complete records of any modification of an established method used in testing are maintained. | U |
| Records of calibration for laboratory equipment and gauges are maintained.<br>Outside laboratory. | U |
| Distribution records contain the name, strength, description, dosage form, lot number, quantity of the drug product and the date shipped as well as the name and address of the consignee. | Yes |
| Firm has written procedures for handling all complaints which include provisions for review by the quality control unit. Procedures are followed.<br>No complaints. | U |
| A written record of each complaint is maintained in a file designated for drug product complaints. Records are maintained at the establishment where the drug product was manufactured, or if kept at another facility, are readily retrievable. | U |
| Records of complaints include the name, strength and lot number of the drug as well as the name of the complainant, nature of the complaint and response to complaint. | U |
| The firm maintains separate, complete and readily retrievable records of distribution into the state of Florida. | Yes |
| The firm has SOPs for adverse event reporting to the FDA. | Yes |
| Firm has record of adverse event reports submitted to FDA. | U |
| ADEs are adequately reported to FDA. Reasons for not reporting an ADE are documented. | U |

# 503b Outsourcing Inspection

Insp #

File #

**Remarks:**
**Policies and environmental conditions are documented in Instant GMP.**
**'U'= unable to determine. Inspection completed by Senior Pharmacists, Mala Cullipher and Gillian Staikos with Hale Dimetry, Carl Smith, Denise Lightbody, Meena Ragheb.**

I have read and have had this inspection report and the laws and regulations concerned herein explained and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Inspector Signature

Mala Cullipher

Date: 11-9-22

Representative

hale dimetry

Date: 11-9-22

**State Inspection Review** Date(s): 08Nov2022-09Nov2022

*Any **NO** responses from State regarding the inspection or any that received a **YES** or **U** but had a comment noted by an inspector that PQ Pharmacy could further clarify will be addressed within this document.*

(See **Attachment A** for State Inspection Sheet).

1. Received a **NO**

| |
|---|
| **State Inspection:** Investigations include findings, conclusion and follow-up<br>**State Comment:** *"DEV2022019 - OOS Potency of Prednisolone Sodium Phosphate 1%/Moxifloxacin HCl 0.5%/Bromfenac Sodium Sesquihydrate 0.09% - no indication that the lot was not released. Batch Record states batch was not released".* |

This specific lot was associated with two separate deviations. Deviation DEV2022019 noted by the State Inspector was regarding the preliminary low potency result. ARL (third party lab) opened an OOS investigation and it was noted that the preliminary result was incorrect and was due to a lab error; deviation was closed on 14Apr2022 **(Attachment B).**

This lot was also associated with Deviation DEV2022027, opened 18Apr2022. This deviation was opened to document the non-viable particle counters not working at the time of aseptic filling of this lot. It is documented within this deviation record that due to the inability to recover non-viable data during aseptic filling operations, the batch was not released for sale **(Attachment C).**

2. Received a **NO**

| |
|---|
| **State Inspection:** Personnel have been periodically trained in core competencies; visual observation is conducted to confirm personnel have necessary skills (I.e., Hand hygiene and garbing, aseptic manipulations, cleaning and disinfecting.<br>**State Comment:** *BM support production personnel unable to demonstrate proper aseptic technique- did not sanitize gloved hands with sIPA prior to reaching in from the side and removing finished droptainers containing Prednisolone/Moxifloxacin HCl/Bromfenac, specifically, LOT: PMB110722IJ.* |

During dosing of ophthalmic solutions, specifically lot PMB110722IJ, the support operator's role is to assist the two operators filling and capping in the ISO 5 by wiping/shedding in supplies and removing the filled/capped droptainers from the ISO 5, thus limiting the operators directly involved in the critical aseptic manipulations from entering and exiting the PEC multiple times. This technique has been qualified at minimum in triplicate with the same personnel during media fill simulations; all resulting in passing results.

Units are pulled from the beginning, middle and end of the filling process; this ensures uniformity throughout the entirety of the batch. These units are used for Sterility testing samples per SOP *S700400 Sampling of In-Process Bulk and Final Products* **(Attachment D).** Sterility testing results for lot PMB110722IJ were sterile **(Attachment E).**

While the operator failed to follow proper aseptic technique when entering the ISO 5, the droptainers that the Inspector witnessed BM removing from the hood were completely sealed.

A training session was performed by Operations Supervisor with operator BM on proper aseptic technique includes spraying hands EVERY time you are entering the ISO 5 whether you are acting as support or directly involved in the filling process. In addition to spraying hands, Operations Supervisor reviewed when and how often glove changes should be performed **(Attachment F)**.

After a retraining session was performed, on 11Nov2022 operator BM was performing support duties under the direct supervision of the Quality Manager during filling operations of Lot: PMB110922IJ.An observation was documented by Quality Manager **(Attachment G)**.

3. Received a **NO**

**State Inspection:** Certifications of primary and secondary engineering controls are current and are conducted under dynamic, worst-case conditions with the maximum number of personnel allowed per SOP present.
**State Comment:** *Certifications: Medrep Sept 19-23,2022 not completed under dynamic conditions. Prior certification in March 2022- conducted under dynamic conditions for smoke study. Medrep 11/1/2022 - conducted under dynamic conditions, but preliminary report does not specify the number of personnel that were present – this must be completed per policy every 6 months. SOP does not specify the worst-case dynamic conditions with the maximum number of personnel present.*

During semi-annual certification of the ISO Classified areas Medrep failed to perform non-viable dynamic testing and had to reschedule to come back to perform dynamic testing (11/01). The report for the dynamic non-viable testing that Medrep provided noted the particle counts but did not include the number of personnel present during sample. A change request was submitted to revise SOP *S117000 Smoke Studies and Certification of ISO Classified Areas* to include that the Medrep or other qualified third-party vendor shall include the number of personnel present at the time of sampling and also to state the maximum validated number of personnel for ISO 7 areas is 5 operators **(Attachment H)**.

4. Received a **NO**

**State Inspection:** The facility has validated the effectiveness of the cleaning solutions
**State Comment:** *No validation for 10-minute dwell time of Spor Klenz or Vesta Syde; Chamber brite for equipment. Cleaning effectiveness studies in-process with Focus Labs.*

During commissioning stages of PQ Pharmacy facility, cleaning along with environmental monitoring took place to evaluate the effectiveness of the chosen cleaning agents along with our written cleaning procedure. The data collected from the study and provided literature from Steris, was used as justification in the cleaning effectiveness until our annual collection and review of facility specific microbial recoveries could take place.

On 16Nov2022, *SOP S302002 Facility Cleaning and Maintenance* was revised to replace the 10-minute contact time with 30-minute contact time pending DET study completion **(Attachment I)**.

On 04Nov2022, a quote was signed with qualified third-party lab, FOCUS Laboratories for a DET study **(Attachment J)**; evaluating PQ Pharmacy's selected antimicrobial cleaning agents (Sporklenz, Vesta Syde SQ and sIPA), contact times, facility specific surfaces and organisms.

Estimated completion of the DET study 4-6 weeks.

5. Received a **NO**

| |
|---|
| **State Inspection:** The facility has qualified their contract labs.<br>**State Comment:** FOCUS-visit completed but ARL qualified through questionnaire. |

On-site audit for FOCUS Laboratories was performed on 01Apr2022, in addition to questionnaire, accreditations, and full lab provided quality packet **(Attachment K)**.

ARL is located in Oklahoma and an on-site audit has not been performed at this time. Qualification of laboratory was performed via detailed questionnaire, quality agreement, accreditations and review of last FDA Inspection and response **(Attachment L)**.

6. Received a **NO**

| |
|---|
| **State Inspection:** Endotoxin testing is conducted on all batches<br>**State Comment:** Endotoxin testing on Mitomycin Irrigation Solution and not Ophthalmic Drops |

Endotoxin Testing is performed on all irrigations and injectable drug products produced at PQ Pharmacy. Endotoxin <85> testing is not performed on topical ophthalmic drops; specifically, Prednisolone Sodium Phosphate/ Moxifloxacin HCL/Bromfenac 1%/0.5%/0.09% Ophthalmic Drops (PMB) and Prednisolone Sodium Phosphate/ Moxifloxacin HCL 1%/0.5% Ophthalmic Drops (PMO). PQ Pharmacy PMB/PMO ophthalmic drops are not labeled and nonpyrogenic. Additionally, FDA Guidance references USP Chapter <771> ophthalmic Products, Quality Tests stating that typically, endotoxin testing is not required for topically administered ophthalmic products (page 25 of *Current Good Manufacturing Practice – Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B)* **(Attachment M)**.

7. Received a **NO**

| |
|---|
| **State Inspection:** Batch production and control records are accurate and complete.<br>**State Comment:** Multiple batch records for PMB1/0.5/0.09 calculation page on page 11 of 16: total volume made is changed all calculations changed. Material used in process- batch record does not include all items, manually documented. Master batch record has been changed total volume compounded blank.<br>PMB 1/0.5/0.09 5.6mL - lot PMB102522IJ, pg 15 of 16 Post Qualification count not documented.<br>Media Fill TSB072121MM and TSB062322SV-BR states monoject, however BD syringes were used and this was not corrected. |

At the time of the State Inspection, batch records had a change request in process to revise the calculations page so that the batch size and proceeding calculations are left blank to eliminate the cross throughs if a different volume is being produced; example **(Attachment N)**.

Additionally, the materials pages of the batch records were revised to add additional blank spaces in the materials section for operators to document any additional supplies used.

In reference to the Post Qualification page, this section of the batch record lacked uniformity as to what number shall be documented on the count line – some cases the total number of units after testing units were pulled was documented, other cases the total number of dosed units was documented. Moving forward the total number of units dosed prior to any units being pulled for retains, rejects or testing will be the count documented.

A typographical error was discovered in the Pump to Syringe Media Fill Protocol; in the filling section of the protocol the materials table included prepopulated manufacturer of the syringes used incorrectly as Monoject, when BD syringes were actually used. Operators were still documenting the correct BD lot umber of the syringes used in the media fill – but not all were correcting the prepopulated "monoject" to "BD". The Pump to Syringe protocol was revised to remove Monoject from the materials sections; example **(Attachment O)**.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 555 Winderley Place, Suite 200<br>Maitland, FL 32751<br>(407)475-4700 Fax:(407)475-4768<br>ORAPHARM2_RESPONSES@fda.hhs.gov | 10/11/2022-10/27/2022*<br>FEI NUMBER<br>3017374013 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Hale N. Dimetry, , President

| FIRM NAME | STREET ADDRESS |
|---|---|
| PQ Pharmacy LLC | 15215 Technology Dr |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Brooksville, FL 34604-0690 | Outsourcing Facility (503B) |

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:**
Quality System

## OBSERVATION 1

The quality control unit lacks authority to review production records to assure that no errors have occurred and fully investigate errors that have occurred.

The quality control unit (QCU) did not fully investigate laboratory test results before releasing finished drug products.

Specifically,

A. Your firm did not have a validated test method for assay testing of your drug products, Prednisolone Sodium Phosphate/Moxifloxacin HCL/Bromfenac 1%/0.5%/0.09% and Prednisolone Sodium Phosphate/Moxifloxacin HCL 1%/0.5% ophthalmic solutions before release and distribution of final product. Lot PMO41322SV assigned no beyond use date (BUD) was used for your third-party test method validation for both ophthalmic solutions that was completed on 10/27/2022. Prior to 10/27/2022, the following lots were distributed to customers with final assay results using an unvalidated test method:

- PMB041922SV 8.6mL starting on 05/16/2022- 10 units
- PMB060322SV 5.6mL starting on 07/06/2022- 273 units
- PMB072522SV 5.6mL starting on 08/10/2022- 921 units

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| | Joanne E King, Investigator<br>Kayla V Sprague, Investigator | X | 10/27/2022 |

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 555 Winderley Place, Suite 200<br>Maitland, FL 32751<br>(407)475-4700 Fax:(407)475-4768<br>ORAPHARM2_RESPONSES@fda.hhs.gov | 10/11/2022-10/27/2022*<br>FEI NUMBER<br>3017374013 |

| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | |
|---|---|
| Hale N. Dimetry, , President | |
| FIRM NAME<br>PQ Pharmacy LLC | STREET ADDRESS<br>15215 Technology Dr |
| CITY, STATE, ZIP CODE, COUNTRY<br>Brooksville, FL 34604-0690 | TYPE ESTABLISHMENT INSPECTED<br>Outsourcing Facility (503B) |

- PMB072722SV 8.6mL starting on 08/15/2022- 834 units
- PMB080322SV 5.6mL starting on 09/20/2022- 700 units
- PMO082922SV 5.6mL starting on 09/23/2022- 200 units

B. The quality control unit (QCU) did not fully investigate the low potency assay test result of an in process drug sample and the high potency assay test result for the finished drug product sample of mitomycin 1 mg/ml (40 mg/40 ml) syringes for bladder irrigation before the release of the batch for use in patients. The in-process sample consisting of one 10 ml syringe containing 5 ml contract lab test result under lab # 821095 was obtained following an unwritten high performance/pressure liquid chromatography (HPLC) test method for mitomycin 1mg/ml (40 mg/40ml) syringes for bladder irrigation lot MIT030722MM beyond use date (BUD) 6/5/2022 for assay and was out of the specification 90 % - 120 % as follows:

- 88.0 % on 3/9/2022
- 80.4 % on 3/18/2022
- 79.9 % on 3/18/2022

Based on the in-process test result 88.0 % obtained on 3/9/2022 the bulk in process mitomycin 1mg/ml in (40 mg/40 ml) syringes for bladder irrigation lot MIT030722MM BUD 6/5/2022 was adjusted and reworked on 3/16/2022 with 0.539 g of mitomycin C USP bulk drug substance lot AD191102AV. This batch was assigned the adjusted lot number MIT030722MM-R and resubmitted for finished product testing. The finished product sample consisted of nine 50 ml syringes each containing 40 mg/40 ml of mitomycin (1mg/ml) lot MIT030722MM-R BUD "5/6/2022" under the lab # 824079.

The finished product contract lab test result following an unwritten HPLC test method for mitomycin

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| DEPARTMENT OF HEALTH AND HUMAN SERVICES<br>FOOD AND DRUG ADMINISTRATION | |
|---|---|
| DISTRICT ADDRESS AND PHONE NUMBER<br>555 Winderley Place, Suite 200<br>Maitland, FL 32751<br>(407)475-4700 Fax:(407)475-4768<br>ORAPHARM2_RESPONSES@fda.hhs.gov | DATE(S) OF INSPECTION<br>10/11/2022-10/27/2022*<br>FEI NUMBER<br>3017374013 |
| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED<br>Hale N. Dimetry, , President | |
| FIRM NAME<br>PQ Pharmacy LLC | STREET ADDRESS<br>15215 Technology Dr |
| CITY, STATE, ZIP CODE, COUNTRY<br>Brooksville, FL 34604-0690 | TYPE ESTABLISHMENT INSPECTED<br>Outsourcing Facility (503B) |

(1mg/ml) 40 mg/40 ml syringes for bladder irrigation lot MIT030722MM-R BUD "5/6/2022" for assay was out of the specification 90 % -120 % as follows:

- 125.2 % on 3/18/2022

The finished product contract lab test result following the test method *Analysis of Mitomycin by HPLC (Stability Indicating, cGMP) AMI-1150 V. 6* for mitomycin (1 mg/ml) 40 mg/40 ml syringes for bladder irrigation lot MIT030722MM-R BUD "5/6/2022" for assay was within specification 90 % to 120 % as follows:

- 115.5 % on 3/23/2022
- 115.8 % on 3/23/2022

The average of the 3/23/2022 contract lab test results, 115.7 %, was reported as the test result for the assay and used for the release testing for 92 syringes, according to the batch record documentation, of mitomycin (1 mg/ml) 40 mg/40 ml syringes for bladder irrigation lot MIT030722MM-R BUD "5/6/2022" on 4/5/2022. Documentation provided listed that 82 of these syringes were distributed for use from 4/4/2022-4/13/2022.

Mitomycin (1 mg/ml) 40 mg/40 ml syringes for bladder irrigation lot MIT030722MM-R BUD "5/6/2022" was used for the test method validation under lab # 825821 and the validation was completed on 4/26/2022.

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**OBSERVATION 2**

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Joanne E King
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
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| 555 Winderley Place, Suite 200<br>Maitland, FL 32751<br>(407)475-4700 Fax:(407)475-4768<br>ORAPHARM2_RESPONSES@fda.hhs.gov | 10/11/2022-10/27/2022*<br>FEI NUMBER<br>3017374013 |

| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | |
|---|---|
| Hale N. Dimetry, , President | |
| FIRM NAME<br>PQ Pharmacy LLC | STREET ADDRESS<br>15215 Technology Dr |
| CITY, STATE, ZIP CODE, COUNTRY<br>Brooksville, FL 34604-0690 | TYPE ESTABLISHMENT INSPECTED<br>Outsourcing Facility (503B) |

Specifically,

Your firm compounded Prednisolone Sodium Phosphate/Moxifloxacin HCL 1%/0.5%/mL Ophthalmic Solution Lot number: PMO052622SV on May 26, 2022, into a filtered bulk bag and held it for 13 days before filing into its finished form (droptainers) on June 8, 2022. Your firm's established hold time for this drug product is 8 days. This discrepancy was not identified by anyone including your quality unit and no investigation was performed. Additionally, operator SV who performed the manufacturing of this compound was only qualified for 7 days according to your media fill hold time study. This batch was released by your quality unit on July 01, 2022 for sale but was not distributed due to no client need before its product expiration date.

Laboratory Control System

**OBSERVATION 3**
An adequate number of batches of each drug product are not tested nor are records of such data maintained to determine an appropriate expiration date.

Specifically, the beyond use date (BUD) for mitomycin (1mg/1ml) 40mg/40 ml in 50 ml syringe for bladder irrigation was changed from 30 days to 90 days on 5/4/2022, 90 days to 130 days on 7/8/2022 and from 130 to 180 days for lot MIT081622IJ. This BUD was extended based on the stability batch contract lab test results for lot MIT122821MM. This stability batch was not tested using a contract test lab validated test method for assay until after the validation of the test method which according to documentation occurred on 4/26/2022.

**OBSERVATION 4**
The written stability program for drug products does not include reliable test methods.

Specifically, the stability batch MIT122821MM was tested at the time points 0 and 30 days using an un-

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | |
|---|---|
| Hale N. Dimetry, , President | |
| FIRM NAME | STREET ADDRESS |
| PQ Pharmacy LLC | 15215 Technology Dr |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Brooksville, FL 34604-0690 | Outsourcing Facility (503B) |

validated contract test lab test method for assay.

Facilities and Equipment System

**OBSERVATION 5**

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically, the 10 minutes contact time listed in you *SOP S110108 Deactivation, Decontamination, Cleaning, and Disinfection Program (DDCD) for Receiving, Storage, and Manufacturing Areas Sections 7.1.1.1 and 7.2.4* and *SOP S302002 Facility Cleaning and Maintenance Section 7.1.5.4.1* was not in keeping with the Spor-Klenz manufacturer's recommended undiluted 30 minute contact time.

Food, Drug, and Cosmetic Act

**OBSERVATION 6**

Your outsourcing facility did not submit a report to FDA identifying the drugs compounded during the previous six month period.

Specifically, the following products were compounded during the reporting period 2022-1 according to your production log batch record, but were not identified on your report dated May 31, 2022 (2022-1):

1. Prednisolone Sodium Phosphate/ Moxifloxacin HCL/Bromfenac 1%/0.5%/0.09% Ophth Solution produced March 3, 2022, in 5 mL volume was not reported for 2022-1
2. Prednisolone Sodium Phosphate/Moxifloxacin 1%/0.05% Ophth Solution produced May 26, 2022, in 5 mL volume was not reported for 2022-1
3. Prednisolone Sodium Phosphate/Moxifloxacin 1%/0.05% Ophth Solution produced May 26, 2022, in 8 mL volume was not reported for 2022-1.

**OBSERVATION 7**

Joanne E King
Investigator
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| | Joanne E King, Investigator<br>Kayla V Sprague, Investigator | X | 10/27/2022 |

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 555 Winderley Place, Suite 200<br>Maitland, FL 32751<br>(407)475-4700 Fax:(407)475-4768<br>ORAPHARM2_RESPONSES@fda.hhs.gov | 10/11/2022-10/27/2022* |
| | FEI NUMBER<br>3017374013 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Hale N. Dimetry, , President

| FIRM NAME | STREET ADDRESS |
|---|---|
| PQ Pharmacy LLC | 15215 Technology Dr |
| CITY, STATE, ZIP CODE, COUNTRY<br>Brooksville, FL 34604-0690 | TYPE ESTABLISHMENT INSPECTED<br>Outsourcing Facility (503B) |

Your outsourcing facility did not submit a report to FDA upon initial registration as an outsourcing facility identifying the drugs compounded during the previous six month period.

Specifically,

Your outsourcing facility did not submit a report to FDA identifying the drugs compounded or no products to report at the time of initial registration, October 29, 2020, and December 2020.

***DATES OF INSPECTION**
10/11/2022(Tue), 10/12/2022(Wed), 10/13/2022(Thu), 10/14/2022(Fri), 10/17/2022(Mon), 10/18/2022(Tue), 10/19/2022(Wed), 10/20/2022(Thu), 10/26/2022(Wed), 10/27/2022(Thu)

X Kayla V. Sprague -S Digitally signed by Kayla V. Sprague -S Date: 2022.10.27 16:16:40 -04'00'

Joanne E King Investigator Signed By: 1306174897 Date Signed: 10-27-2022 15:06:58

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| | Joanne E King, Investigator<br>Kayla V Sprague, Investigator | X | 10/27/2022 |

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

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ATTN: Acting Division Director
US FDA Tampa District Office
555 Winderley Place
Suite 200
Maitland, FL 32751
Cc: Joanne E King, Investigator
Kayla V Sprague, Investigator

November 17,2022

Dear Acting Division Director,

PQ Pharmacy acknowledges the observations cited during the FDA Inspection conducted from 10/11/2022 - 10/27/2022. Our organization takes responsibility to correct the observed conditions and will do so as described within this document; including corrective actions and timelines where appropriate. Additionally, we would like to take this opportunity to provide clarifying data for observations where the information we presented may not have been clearly communicated. PQ Pharmacy relied on "Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act Guidance for Industry", Enforcement Policy Regarding the Use of Limited Stability Testing to Assign a BUD, literature, potency overtime testing using validated testing method by FDA registered third-party lab (ARL) and familiarity with the products when assigning BUDs while stability studies were in-process.

Please include a redacted version of this response if posting PQ Pharmacy's 483 findings on the FDA.gov website.

PQ Pharmacy wants to emphasize the commitment to correcting the observations noted by the inspectors as we strive to include efficient quality processes throughout each aspect of our organization while focusing on continuous quality improvement.

Regards,

Hale N. Dimetry, Pharm. D.

President, PQ Pharmacy

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PRECISION QUALITY

**Attachment Appendix**

| | |
|---|---|
| Attachment A | Sample Requests from ARL for Method Suitability/Validations |
| Attachment B | Letter from ARL Regarding Analytical Methods |
| Attachment C | Original CoAs for PMB |
| Attachment D | Retest CoAs for PMB |
| Attachment E | SOP S700400 Sampling of In-Process Bulk and Final Product |
| Attachment F | Email from ARL Providing Preliminary Results for the MIT030722MM Potency of 88% |
| Attachment G | ARL OOS Investigation Regarding MIT030722MM Potency Result of 88% |
| Attachment H | ARL OOS Investigation Regarding MIT030722MM-R Potency Result |
| Attachment I | CoAs for MIT030722MM-R (Final) |
| Attachment J | Deviation DEV2022020 |
| Attachment K | Method Suitability Report |
| Attachment L | 603003-F Label Control and Reconciliation Form Version 1 |
| Attachment M | 603003-F Label Control and Reconciliation Form Version 2 |
| Attachment N | Drugs for Destruction Log and Pick up Receipt |
| Attachment O | ARL Testing Summary Report |
| Attachment P | SOP S601002 Validation of Aseptic Processes by Simulation (Media Fill) |
| Attachment Q | Quality Batch Release Checklist 103009F |
| Attachment R | SOP S103009 Quality Review for Batch Release and Final Disposition |
| Attachment S | Media Fill Protocols |

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| Attachment T | Personnel Training Spreadsheet |
| Attachment U | Mitomycin C Literature |
| Attachment V | CoAs for Potency Overtime MIT122821MM |
| Attachment W | Stability Study Summary's for Mitomycin 1mg/mL Bladder Irrigation MIT061522MM, MIT062222MM, MIT062922MM |
| Attachment X | SOP S700250 Stability Program for Finished Drug Products |
| Attachment Y | ARL Mitomycin Bladder Irrigation Stability Study Protocol PRO-1003-V1 |
| Attachment Z | Steris Literature |
| Attachment AA | Steris Letter |
| Attachment BB | SOP S302002 Facility Cleaning and Maintenance |
| Attachment CC | June/July Email Correspondence Between PQ and Reporting Support |
| Attachment DD | November Email Correspondence Between PQ and Reporting Support |
| Attachment EE | SOP S118000 Electronic Drug Reporting |
| Attachment FF | 2022-1 Corrected Electronic Drug Reporting |
| Attachment GG | Corrected Initial Electronic Drug Reporting |

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**Observation 1**

*The quality control unit lacks authority to review production records to assure that no errors have occurred and fully investigate errors that have occurred.*

*The quality control unit (QCU)did not fully investigate laboratory test results before releases finished drug products.*

*Specifically,*

A. *Your firm did not have a validated test method for assay testing of your drug products, Prednisolone Sodium Phosphate/Moxifloxacin HCl/Bromfenac 1%/0.5%/0.09% and Prednisolone Sodium Phosphate/ Moxifloxacin HCl 1%/0.5% ophthalmic solutions before release and distribution of final product. Lot PMO041322SV assigned no beyond use date (BUD) was used for your third – party test method validation for both ophthalmic solutions that was completed on 10/27/2022. Prior to 10/27/2022, the following lots were distributed to customers using an unvalidated test method:*
   - *PMB041922SV 8.6mL starting on 05/16/2022 - 10 units*
   - *PMB060322SV 5.6mL starting on 07/06/2022 - 273 units*
   - *PMB072522SV 5.6mL starting on 08/10/2022 - 921 units*
   - *PMB072722SV 8.6mL starting on 08/15/2022 - 834 units*
   - *PMB080322SV 5.6mL starting on 09/20/2022 - 700 units*
   - *PMO082922SV 5.6mL starting on 09/23/2022 - 200 units*

B. *The quality control units (QCU) did not fully investigate the low potency assay test result of an in-process drug sample and the high potency assay test result for the finished drug product sample of Mitomycin 1mg/mL (40mg/40mL) syringes for bladder irrigation before the release of the batch for use in patients. The in-process samples consisting of one 10mL syringe container 5mL contract lab test result under lab #821095 was obtained following an unwritten high performance /pressure liquid chromatography (HPLC) test method for Mitomycin 1mg/mL (40mg/40mL) syringes for bladder irrigation lot MIT030722MM beyond use date (BUD) 6/5/2022 for assay and was out of specification as follows:*
   - *88.0 % on 3/9/2022*
   - *80.4 % on 3/18/2022*
   - *79.9 % on 3/18/2022*

   *Based on the in-process test result 88.0 % obtained on 3/9/2022 the bulk in process mitomycin 1mg/ml in (40 mg/40 ml) syringes for bladder irrigation lot MIT030722MM BUD 6/5/2022 was adjusted and reworked on 3/16/2022 with 0.539 g of mitomycin C USP bulk drug substance lot AD191102AV. This batch was assigned the adjusted lot number MIT030722MM-R and*

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*resubmitted for finished product testing. The finished product sample consisted of nine 50 ml syringes each containing 40 mg/40 ml of mitomycin (1mg/ml) lot MIT030722MM-R BUD "5/6/2022" under the lab # 824079.*

*The finished product contract lab test result following an unwritten HPLC test method for mitomycin (1mg/ml) 40 mg/40 ml syringes for bladder irrigation lot MIT030722MM-R BUD "5/6/2022" for assay was out of the specification 90 % -120 % as follows:*

- *125.2 % on 3/18/2022*

*The finished product contract lab test result following the test method Analysis of Mitomycin by HPLC (Stability Indicating, cGMP) AMI-1150 V. 6 for mitomycin (1 mg/ml) 40 mg/40 ml syringes for bladder irrigation lot MIT030722MM-R BUD "5/6/2022" for assay was within specification 90 % to 120 % as follows:*

- *115.5 % on 3/23/2022*
- *115.8 % on 3/23/2022*

*The average of the 3/23/2022 contract lab test results, 115.7 %, was reported as the test result for the assay and used for the release testing for 92 syringes, according to the batch record documentation, of mitomycin (1 mg/ml) 40 mg/40 ml syringes for bladder irrigation lot MIT030722MM-R BUD "5/6/2022" on 4/5/2022. Documentation provided listed that 82 of these syringes were distributed for use from 4/4/2022-4/13/2022. Mitomycin (1 mg/ml) 40 mg/40 ml syringes for bladder irrigation lot MIT030722MM-R BUD "5/6/2022" was used for the test method validation under lab # 825821 and the validation was completed on 4/26/2022.*

**Observation 1 Response:**

**CAPA2022005 was opened to remediate and mitigate future instances in which PQ Pharmacy would use methods before the final Method Suitability report is provided. The CAPA record shall include mitigation, remediation and corrective and preventative action(s).**

**Observation 1, Part A Response:**

PQ Pharmacy recognizes the failure to assign a BUD to Method Suitability/Validation lot PMO041322SV. This lot was prepared in different volumes and product iterations requested by qualified third-party lab, ARL to perform method suitability and validation testing only; no product was distributed from this lot **(Attachment A)**.

Additionally, PQ Pharmacy relied on referenced validated method statements on the release CoAs by FDA registered third-party lab, ARL. PQ Pharmacy acknowledges the failure to receive the signed/completed method suitability report prior to releasing the above-mentioned lots of PMB/PMO; although many attempts were made.

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**Root Cause(s)/Potential Root Cause(s):**

**RC1:** Lack of BUD procedure on how to assign BUD during method suitability and validation batches.

**RC2:** ARL qualified third-party lab failed to sign the PMB/PMO Method Suitability protocol at time of completion.

**RC3:** PQ Pharmacy failed to obtain and review protocol prior to release of product as we relied on referenced validated method statements on the provided CoAs.

**Correction(s)/Mitigation(s):**

**C1:** On 02Nov2022 a call was had with ARL senior chemist Dr. Quang Liu and PQ Pharmacy Quality Manager and Senior Management to discuss the delay in providing the completed report and the comparison between the in-house method and the AMI-2085 method. Data was provided stating the parameters of the analytical methods used for in-house assay testing using HPLC are scientifically identical to PQ Pharmacy's specified validated HPLC method (AMI-2085) **(Attachment B)**.

**C2:** Review of the CoAs for the potency tests performed for batch release on the mentioned lots were performed **(Attachment C)**.

**C3:** Samples from the above-mentioned lots were sent for potency retesting on 11/07/2022 using validated method AMI-2085; all retests reported with passing results **(Attachment D)**.

**Corrective Action(s):**

**CA1:** SOP *S700400 Sampling of In-Process Bulk and Final Products* was revised to state during method suitability and validation batches the BUD of the Raw Materials/APIs and excipients shall be used as the default BUD of the product being submitted to the lab, but not to exceed 12 months. This revision was implemented on 17Nov2022. **(Attachment E)**

**CA2:** Additionally, a statement was added to SOP *S700400 Sampling of In-Process Bulk and Final Products* stating all validations must be completed, reviewed and signed by all documented personnel prior to the method being used in release testing.

CoA method statements shall not be used in lieu of completed method suitability/validation report. **(Attachment E)** This revision will be implemented on 17Nov2022

**Observation 1, Part B Response:**

PQ Pharmacy performed in-process potency testing to ensure final product specifications were met for bulk solutions during the initial batches of Mitomycin 1mg/mL. A rework of an additional 0.589g was

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performed on this lot after preliminary results were reported at 88% **(Attachment F).** ARL performed an Investigation for the OOS result **(Attachment G).** The 10L bulk solution bag was incorrectly labeled with a BUD of 90 days (6/05/2022) due to a typographical error in lieu of 5/06/2022 (60 days).

Quality Unit released lot: MIT030722MM-R on 4/05/2022 after receiving and reviewing final OOS ARL investigation **(Attachment H),** final result CoA that noted validated method AMI-1150 was used **(Attachment I, )** and completion of Deviation DEV2022020 on 4/05/2022 **(Attachment J).** MIT030722MM-R was released with an assigned BUD of 60 days (5/06/2022).

Additionally, FDA noted within the observation stated *"Mitomycin (1mg/mL) 40mg/40mL syringes for bladder irrigation lot MIT030722MM-R BUD "5/6/2022" was used for the test method validation under lab #825821 and the validation was completed on 4/26/2022".* However, Lot MIT030722MM-R was not used for Potency Method Suitability/Validation which was completed on 4/26/2022 and was used for the Sterility Method Suitability **(Attachment K).**

**Root Cause(s)/Potential Root Cause(s):**

**RC1:** Quality Unit failed to request raw analytical data on the retests performed in ARL's OOS Investigation and relied on information written within the report without further explanation behind the lab error.

**RC2:** Quality Unit failed to obtain, and review completed ARL Method Suitability Report prior to the method being used for batch release. Further, PQ Pharmacy relied on the statement on the CoA stating AMI-1150 validated method was used before receipt of signed validation report.

**RC3:** Detailed labeling form that includes labels used for bulk bags were not a part of the batch records at the time this lot was produced.

**Correction(s)/Mitigation(s):**

**C1:** Phone conference was held with FDA investigators, PQ Pharmacy Quality Manager and Senior Management to review the Investigation and analytical packet for the potency method suitability. ARL Chemist reported that the 125.2% could not be replicated and was a lab error, thus was not included in the final reported result of 115.7%.

**C2:** Review of CoAs for potency testing for lot: MIT030722MM-R was performed, and the following was noted **(Attachment I).**

- On 3/23/2022 the CoA was released with the final potency results 115.7%.
- On 4/04/2022 the CoA was revised to state AMI-1150 was used to run the sample.
- On 6/15/2022 the CoA was further revised to remove the statement "non-GMP" as the method used to run the sample was the validated AMI-1150.

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**C3:** Review of testing submissions was performed. Lot: MIT030722MM-R was submitted for Method Suitability <71>, in addition to routine release testing for batch release for this product (sterility <71>, subvisible particulate <788>, pH <791>, Potency and Endotoxin <85>).

**Corrective Action(s):**

**CA1:** A statement was added to SOP *S700400 Sampling of In-Process Bulk and Final Products* stating, all validations must be completed prior to release testing **(Attachment E)** This revision was implemented on 16Nov2022.

**CA2:** Additionally, a statement was added to SOP *S700400 Sampling of In-Process Bulk and Final Products* stating all validations must be completed, reviewed and signed by all documented personnel prior to the method being used in release testing. CoA method statements shall not be used in lieu of completed method suitability/validation report. **(Attachment E)** This revision will be implemented on 17Nov2022.

**CA3:** Label Control and Reconciliation Form was made official on 24Jun2022 **(Attachment L)** and was revised on 05Oct2022 **(Attachment M).** This requires signatures from QA personnel to perform a label check on all labels including In-process Testing, Bulk Bag and Final Product prior to personnel printing the full number of labels and applying labels.

**Observation 2**

*The responsibilities and procedures applicable to the quality control unit are not fully followed.*

*Specifically, Your firm compounded Prednisolone Sodium Phosphate/Moxifloxacin HCL 1%/0.5%/mL Ophthalmic Solution Lot number: PMO052622SV on May 26, 2022, into a filtered bulk bag and held it for 13 days before filing into its finished form (droptainers) on June 8, 2022. Your firm's established hold time for this drug product is 8 days. This discrepancy was not identified by anyone including your quality unit and no investigation was performed. Additionally, operator SV who performed the manufacturing of this compound was only qualified for 7 days according to your media fill hold time study. This batch was released by your quality unit on July 01, 2022 for sale but was not distributed due to no client need before its product expiration date.*

**CAPA2022006 was opened to investigate the observation and potential additional deficiencies for root cause(s)/potential root cause(s); specifically, the validated hold-times established during personnel Media Fills. The CAPA record shall include mitigation, remediation and corrective and preventative action (s).**

PHARMA
PRECISION QUALITY

**Observation 2 Response:**

PQ Pharmacy recognizes that the validated hold time per personnel and per product were not followed. Hold times representative to specific operators and product sets will be based on the media fill performed. Routinely, batches are bulked and dosed next business day as in-process potency is only performed the first initial batches of product to ensure accuracy of formulary. Lot PMO052622SV was not distributed and was sent for destruction **(Attachment N).**

**Root Cause(s)/Potential Root Cause(s):**

**RC1:** Bag was held for 13 days due to delay of in-process potency results. Potency results were submitted on 27May2022, and results were not received from the lab until 07Jun2022 **(Attachment O).**

**RC2:** Quality Unit failed to identify the non-conformance upon batch review and failed to open a deviation to document the non-conformity.

**RC3:** Operator(s) failed to verify hold time per media fill validation.

**Correction(s)/Mitigation(s):**

**C1:** A review of all hold times for released drug products produced at PQ Pharmacy took place to ensure that no other batches were affected by this deficiency. No additional deficiencies were discovered.

**Corrective Action(s):**

**CA1:** No units from this lot were distributed. SOP *S601002 Validation of Aseptic Processes by Simulation (Media Fills)* was revised to include in the event that a bag is held over the validated hold time, the bag shall be refiltered prior to being dosed into final containers **(Attachment P).** These revisions were implemented on 16Nov2022.

**CA2:** Media Fill Verification was added to the *Quality Batch Release Checklist 103009F and S 103009 Quality Review for Batch Release and Final Disposition* to verify the personnel validated yield and hold time **(Attachment Q and Attachment R).** These revisions were implemented on 14Nov2022.

Additionally, *SOP 601002 Validation of Aseptic Process by Simulation (Media Fills)* was revised to state the operator's unit yield and bulk bag hold time will be determined by the media fill **(Attachment P).** This revision was implemented on 16Nov2022.

**CA3:** Specific directions were added to the Media Fill protocols to document the number of days the bulk bag was held prior to dosing **(Attachment S).** These revisions were implemented on 16Nov2022.

**CA4:** Personnel Training Spreadsheet where validated yield and due dates for requalification are tracked by Quality was locked to edits but made public to operations personnel so they can verify prior to participating in scheduled production **(Attachment T).** This was made available to all personnel on 31Oct2022.

PHARMA
PRECISION QUALITY

**Observation 3**

*An adequate number of batches of each drug product are not tested nor are records of such data maintained to determine an appropriate expiration date.*

*Specifically, the beyond use date (BUD) for mitomycin (1mg/1ml) 40mg/40 ml in 50 ml syringe for bladder irrigation was changed from 30 days to 90 days on 5/4/2022, 90 days to 130 days on 7/8/2022 and from 130 to 180 days for lot MIT081622IJ. This BUD was extended based on the stability batch contract lab test results for lot MIT122821MM. This stability batch was not tested using a contract test lab validated test method for assay until after the validation of the test method which according to documentation occurred on 4/26/2022.*

**CAPA2022007 was opened to investigate the observation and potential additional deficiencies for root cause(s)/potential root cause(s); specifically, to provide data on utilizing potency over time testing and literature to extend the BUD on Mitomycin 1mg/mL Bladder Irrigation. The CAPA record shall include mitigation, remediation and corrective and preventative action (s).**

**Observation 3 Response:**

PQ Pharmacy recognizes that the BUD for Mitomycin 1mg/mL is assigned based on cited literature **(Attachment U)** and timepoint potency tests performed with validated method **(Attachment V)**. Lot MIT122821MM was used for potency overtime testing only and separate from the 3 current on-going stability studies. Additionally, this lot was not distributed and used for testing purposes only.

It is PQ Pharmacy's understanding of "Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act Guidance for Industry" Specifically Section C, Enforcement Policy Regarding the Use of Limited Stability Testing to Assign a BUD (page 45 and 46), that based on timepoint data using validated test methods and literature regarding the stability of the product, dating could be extended; yet not to exceed 12 months or any of the API or excipients.

Current BUD has been established based on potency testing over time using cGMP validated method. Currently, Mitomycin 1mg/mL Bladder Irrigation has an assigned BUD of 180 days under refrigerated conditions.

**Root Cause(s)/Potential Root Cause(s):**

**RC1:** Lot: MIT122821MM is not a stability lot.

**RC2:** Validated Method AMI-1150 was used and documented on CoAs prior to the completed Method Suitability report being signed by ARL.

PHARMA
PRECISION QUALITY

**Correction(s)/Mitigation(s):**

**C1:** A review of the FDA "Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act Guidance for Industry" Specifically Section C, Enforcement Policy Regarding the Use of Limited Stability Testing to Assign a BUD (page 45 and 46), regarding assigning BUD was performed and the requirements listed in the Guidance were addressed:

- Samples are evaluated following aging under the long-term storage conditions (i.e., temperature and humidity) in ICH Q1A(R2).

*Lot: MIT122821MM used for potency overtime testing was stored per labeled refrigerated conditions.*

- The data from each time point are evaluated against the established specifications for the compounded drug product.

*Testing results were reviewed based on validated method AMI-1150, USP Monograph and the formulary.*

- The BUD is no longer than 12 months

*Assigned BUD is 180 days; 6months.*

- If the data for any test fall outside of the established specifications, the BUD is restricted to the last time point at which the data remained within specifications, or the default BUD (described above) is used.

*All potency timepoint results for MIT122821MM were passing results.*

**C2:** A review of potency overtime testing using validated method AMI-1150 from Lot: MIT122821MM were reviewed **(Attachment V).**

| | | | |
|---|---|---|---|
| Day 104 | 11Apr2022 | HPLC/AMI-1150 | 102.7% |
| Day 162 | 08Jun2022 | HPLC/AMI-1150 | 101.5% |
| Day 213 | 29Jul2022 | HPLC/AMI-1150 | 100.5% |

The BUD was adjusted to 90 days on 04May2022 based on the 11Apr2022 results, to 130 on 08Jul2022 based on 08Jun2022 results and to 180 on 16Aug2022 based on 29Jul2022 results.

**C3:** A review of the full stability studies in-process for Mitomycin 1mg/mL were reviewed; all tests throughout the timepoints were passing results **(Attachment W)**.

Three full stability lots for Mitomycin 1mg/mL are currently in-progress **(Attachment W)**:

- MIT061522MM, estimated report of final timepoint (190): 03Jan2023
- MIT062222MM, estimated report of final timepoint (190): 11Jan2023
- MIT062922MM, estimated report of final timepoint (190): 17Jan2023

PHARMA
PRECISION QUALITY

**Corrective Action(s):**

**CA1:** Additionally, a statement was added to SOP *S700400 Sampling of In-Process Bulk and Final Products* stating all validations must be completed, reviewed and signed by all documented personnel prior to method being used in release testing. CoA method statements shall not be used in lieu of completed method suitability/validation report **(Attachment E).** This revision will be implemented on 17Nov2022.

**Observation 4**

*The written stability program for drug products does not include reliable test methods.*

*Specifically, the stability batch MIT122821MM was tested at the time points 0 and 30 days using an un-validated contract lab test method.*

**CAPA2022008 was opened to investigate the observation and potential additional deficiencies for root cause(s)/potential root cause(s); specifically, to identify and clarify the purpose of lot MIT122821MM. The CAPA record shall include mitigation, remediation and corrective and preventative action (s).**

**Observation 4 Response:**

PQ Pharmacy recognizes that the initial potency test was performed using an unvalidated test method (ARL in-house Method). PQ Pharmacy would like to clarify that all testing performed in stability studies are performed using validated test methods per SOP S *700250 Stability Program for Finished Drug Products* **(Attachment X).** Specifically, Lot: MIT122821MM is not a full stability batch and is only used for testing potency overtime. Additionally, this lot was not distributed and used for testing purposes only. Current BUD has been established based on potency testing over time using cGMP validated method.

**Root Cause(s)/Potential Root Cause(s):**

**RC1:** Potency validations for HPLC AMI-1150 Mitomycin Validated Method were not complete at the time of the testing the first 2 potency timepoints.

**RC2:** Lot: MIT122821MM mentioned in the observation is not a part of the Mitomycin 1mg/mL stability program at PQ Pharmacy. This lot is only tested for potency over time to provide additional data as to the length of stability of the drug product.

PHARMA
PRECISION QUALITY

**Correction(s)/Mitigation(s):**

**C1:** Additional timepoints for lot: MIT122821MM were reviewed; all additional timepoints were tested using the validated method AMI-1150 **(Attachment V).**

**C2:** Three stability lots for Mitomycin 1mg/mL are currently in-progress **(Attachment W):**

- MIT061522MM, estimated report of final timepoint (190): 03Jan2023
- MIT062222MM, estimated report of final timepoint (190): 11Jan2023
- MIT062922MM, estimated report of final timepoint (190): 17Jan2023

Time points for the above-mentioned stability lots follow the PQ Pharmacy stability program requirements as outlined in *SOP 700250 Stability Program for Finished Drug Products* **(Attachment X),** testing Potency AMI-1150, Sterility <71>, Subvisible Particulate <788>, pH <791>, Visual Appearance, Container Closure and Endotoxin <85>. Testing is performed over timepoints 0, 30, 60, 100, 130 and 190, all performed using validated methods according to signed ARL Stability Protocol **(Attachment Y)**

**C3:** Lot: MIT1228221MM was not distributed and used for testing purposes only.

**Corrective Action(s):**

**CA1:** N/A as stability studies performed at PQ Pharmacy are completed using only validated methods.

**Observation 5**

*Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.*

*Specifically, the 10 minutes contact time listed in you SOP S110108 Deactivation, Decontamination, Cleaning, and Disinfection Program (DDCD) for Receiving, Storage, and Manufacturing Areas Sections 7.1.1.1 and 7.2.4 and SOP S302002 Facility Cleaning and Maintenance Section 7.1.5.4.1 was not in keeping with the Spor-Klenz manufacturer's recommended undiluted 30-minute contact time*

**CAPA2022009 was opened to investigate the observation and potential additional deficiencies for root cause(s)/potential root cause(s); specifically, to identify the failure to follow the 30-minute label claim. The CAPA record shall include mitigation, remediation and corrective and preventative action (s).**

PHARMA
PRECISION QUALITY

**Observation 5 Response:**

PQ Pharmacy developed cleaning procedures based on training provided by qualified supplier, Steris, in addition to Environmental Monitoring during commissioning stages and risk assessment.

**Root Cause(s)/Potential Root Cause(s):**

**RC1:** 10-minute contact time was based on on-site training provided by Steris upon ordering Sporklenz cleaning agent.

**RC2:** PQ Pharmacy failed to notice or question the difference in the communicated 10-minute contact time and the label claim of 30-minutes.

**Correction(s)/Mitigation(s)**

**C1:** 30-minute contact time was implemented to match Steris label claim.

**C2:** PQ Pharmacy reviewed Environment Monitoring Trending to assure that the integrity of the ISO classified rooms was not compromised due to the 10-minute contact time. There we no noticeable negative microbial recoveries.

**C3:** PQ Pharmacy Quality Manager and Senior Management met with Steris Management to discuss the variation between contact time of 10-minutes communicated during training and the 30-minute label claim. It was stated by Steris that there are efficacy studies that are completed, and data is in review process by Steris QA and will be made public in the near future. Literature was provided demonstrating that applying a 10-minute contact time has proven the ability to eliminate spores **(Attachment Z)**.

The EU label claim of Sporklenz RTU does instruct the 10-minute contact time. This product is the same product used at PQ Pharmacy which is noted by Steris within the attached letter **(Attachment AA)**.

**Corrective Action(s):**

**CA1:** *S302002 Facility Cleaning and Maintenance* SOP was revised to replace the 10-minute contact time with 30-minute contact time as documented on the Steris label claim for Sporklenz RTU **(Attachment BB)**. This revision will be implemented 17Nov2022.

PHARMA
PRECISION QUALITY

**Observation 6**

*Your outsourcing facility did not submit a report to FDA identifying the drugs compounded during the previous six-month period.*

*Specifically, the following products were compounded during the reporting period 2022-1 according to your production log batch record, but were not identified on your report dated May 31, 2022 (2022-1): 1.Prednisolone Sodium Phosphate/ Moxifloxacin HCL/Bromfenac 1%/0.5%/0.09% Ophth Solution produced March 3, 2022, in 5 mL volume was not reported for 2022-1 2.Prednisolone Sodium Phosphate/Moxifloxacin 1%/0.05% Ophth Solution produced May 26, 2022, in 5 mL volume was not reported for 2022-1 3.Prednisolone Sodium Phosphate/Moxifloxacin 1%/0.05% Ophth Solution produced May 26, 2022, in 8 mL volume was not reported for 2022-1.*

**CAPA2022010 was opened to investigate the observation (*6 and 7*) and potential additional deficiencies for root cause(s)/potential root cause(s); The CAPA record shall include mitigation, remediation and corrective and preventative action (s).**

**Observation 6 Response:**

PQ Pharmacy had been working diligently from the time of the initial attempt for the year 2022 when first experiencing errors. Currently, PQ Pharmacy is actively working with support to correct the filing errors, but still experiencing rejection messages.

**Root Cause(s)/Potential Root Cause(s):**

**RC1:** Electronic Filing Website error message when trying to upload the same product with different fill volumes and NDC errors 30Jun2022.

**RC2:** Electronic Filing Website DUNS error message 15Nov2022.

**RC3:** PQ Pharmacy reached out for technical support to CDER Electronic Drug Registration to attempt to remediate the issue and was not able to correct the error.

**Correction(s)/Mitigation(s):**

**C1:** Reached out to support technician to help with error message via email multiple times beginning on 30Jun2022 **(Attachment CC).**

**C2:** Worked with CDER/FDA support personnel to remediate the error messages we are receiving **(Attachment DD).**

PHARMA
PRECISION QUALITY

**C3:** On 17Nov2022, a phone conference was held with Troy Cu, CDER Technical Information Specialist to further discuss the reoccurring error messages. After the call, PQ Pharmacy was able to correct the initial submission.

**Corrective Action(s):**

**CA1:** *SOP S118000 Electronic Drug Reporting* was created to outline the procedure to semi-annual drug reporting **(Attachment EE).** This procedure was implemented on 14Nov2022.

**CA2:** The error for the NDC was corrected for the PMB with the two different fill volumes, by submitting the formulation under one product NDC and different container NDCs. The DUNs error was able to be corrected by using a single submission. Reporting for 2022-1 was able to be corrected and resubmitted on 17Nov2022 **(Attachment FF)**.

**CA3: Observation 7**

*Your outsourcing facility did not submit a report to FDA upon initial registration as an outsourcing facility identifying the drugs compounded during the previous six-month period.*

*Specifically, Your outsourcing facility did not submit a report to FDA identifying the drugs compounded or no products to report at the time of initial registration, October 29, 2020, and December 2020.*

**CAPA2022010 was opened to investigate the observation (*6 and 7*) and potential additional deficiencies for root cause(s)/potential root cause(s); The CAPA record shall include mitigation, remediation and corrective and preventative action (s).**

**Observation 7 Response:**

PQ Pharmacy acknowledges the failure to submit "no drugs reported" upon initial registration.

**Root Cause(s)/Potential Root Cause(s):**

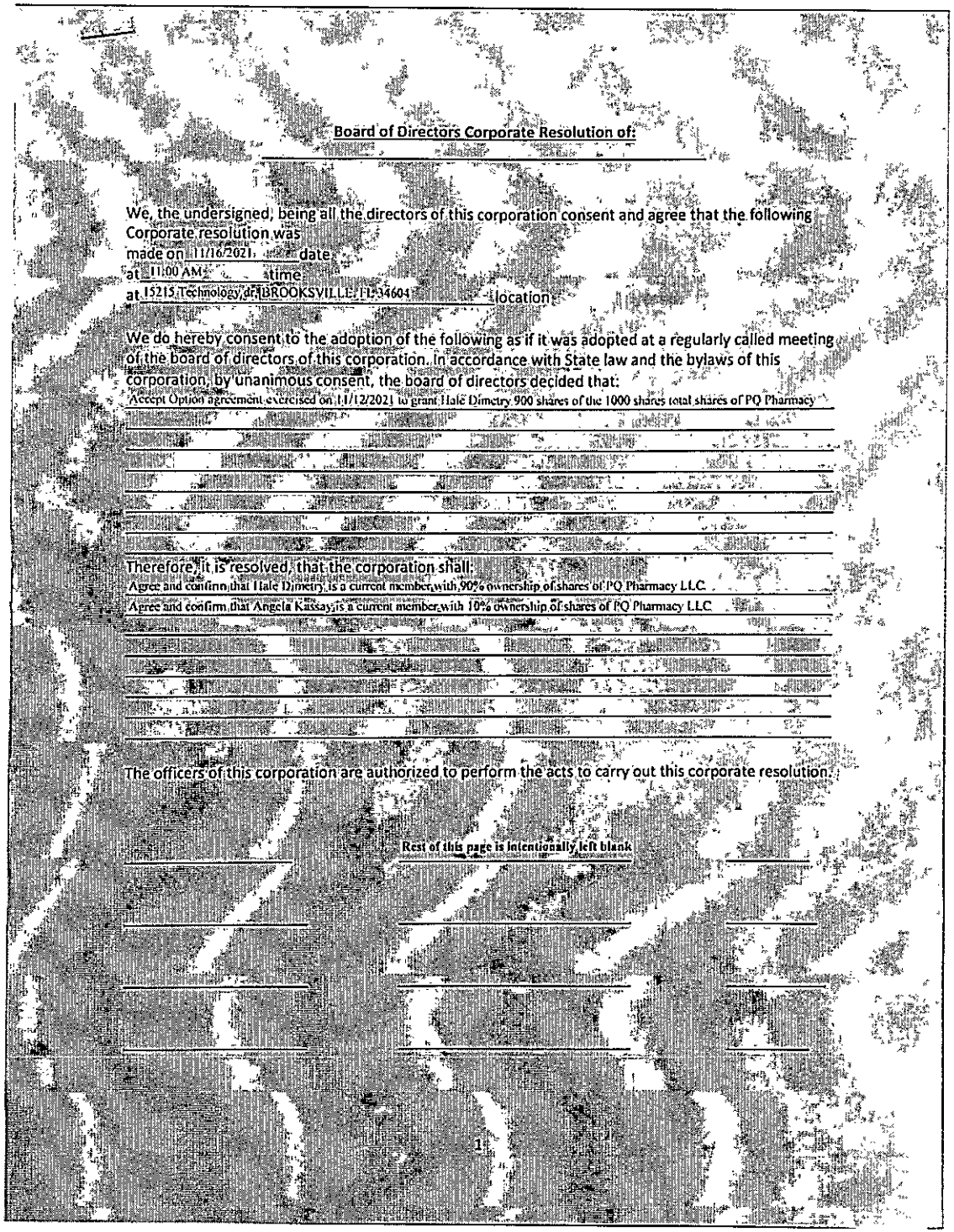
**RC1:** Lack of written procedure to identify the requirements within the FDA Guidance

**Corrective Action(s):**

**CA1:** SOP *S118000 Electronic Drug Reporting* was created to outline the procedure of semi-annual drug reporting **(Attachment EE).**

**CA2:** Resubmitted initial reporting as "no drugs to report" on 17Nov2022 **(Attachment GG)**.

2860



**Board of Directors Corporate Resolution of:**

We, the undersigned, being all the directors of this corporation consent and agree that the following Corporate resolution was
made on 11/16/2021, date
at 11:00 AM time
at 15215 Technology dr, BROOKSVILLE, FL 34604 location

We do hereby consent to the adoption of the following as if it was adopted at a regularly called meeting of the board of directors of this corporation. In accordance with State law and the bylaws of this corporation, by unanimous consent, the board of directors decided that:

Accept Option agreement exercised on 11/12/2021 to grant Hale Dimetry 900 shares of the 1000 shares total shares of PQ Pharmacy

Therefore, it is resolved, that the corporation shall:

Agree and confirm that Hale Dimetry is a current member with 90% ownership of shares of PQ Pharmacy LLC

Agree and confirm that Angela Kassay is a current member with 10% ownership of shares of PQ Pharmacy LLC

The officers of this corporation are authorized to perform the acts to carry out this corporate resolution.

Rest of this page is intentionally left blank

1

2861

Member signature

Hale Dimeby
Printed name

16 November 2021
Date

Member signature

Angela Kassay
Printed name

16 November 2021
Date

The Manager of the Corporation, certifies that the above is a true and correct copy of the resolution that was duly adopted at a meeting of the dated meeting of the board of directors.

Signature of Manager

16/11/2021
Date

Angela Kassay
Printed name of Manager

AC# 10642920

# STATE OF FLORIDA
# DEPARTMENT OF HEALTH
# DIVISION OF MEDICAL QUALITY ASSURANCE

| DATE | LICENSE NO. | CONTROL NO. |
|---|---|---|
| 11/11/2021 | PH 33659 | 129495 |

THE PHARMACY

NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

QUALIFICATION(S):
Outsourcing Facility
Special Sterile Compounding

Expiration Date: **FEBRUARY 28, 2023**
**PQ PHARMACY**
**15215 TECHNOLOGY DR**
**BROOKSVILLE, FL - 34604**

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
State Surgeon General

DISPLAY IF REQUIRED BY LAW

AC# 10642920
STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE
DATE 11/11/2021 | LICENSE NO. PH 33659 | CONTROL NO. 129495
THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF THE LAWS AND RULES OF THE STATE OF FLORIDA.
Expiration Date : FEBRUARY 28, 2023
PQ PHARMACY
QUALIFICATION(S): Outsourcing Facility Special Sterile Compounding

EXPIRATION DATE: **FEBRUARY 28, 2023**

Your license number is PH 33659. Please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the Department in writing of the licensee's current mailing address and practice location address. If you have not received your renewal notice 90 days prior to the expiration date shown on this license, please visit www.FLHealthSource.gov and click "Renew A License" to renew online.

The Medical Quality Assurance Online Services Portal gives you the ability to manage your license to perform address updates, name changes, request duplicate licenses and much more.

It's simple. Log onto your MQA Online Services account today at http://flhealthsource.gov/. Select the "Account Login" button to access your account. For changes to your name, address or to request duplicate licenses, choose your selection from the dropdown list under "Manage My License". Your profession will open for renewal 90 days prior to your expiration date. When the renewal cycle opens for your profession, the "Renew My License" header will automatically display on your license Dashboard.

## IMPORTANT ANNOUNCEMENTS

ARE YOU RENEWAL READY?

The Department of Health will now review your continuing education records at the time of license renewal.

To learn more, please visit
www.FLHealthSource.gov/AYRR

GROUNDS FOR DISCIPLINE

You should be familiar with the Grounds for Discipline found in Section 456.072(1), Florida Statutes, and in the practice act for the profession in which you are licensed. Florida Statutes can be accessed at www.leg.state.fl.us/Statutes

Department of Health

# PQ PHARMACY

## License Number: PH33659

*Data As Of 3/6/2023*

| | |
|---|---|
| **Profession** | Pharmacy |
| **License** | PH33659 |
| **License Status** | CLEAR/ |
| **Qualifications** | Special Sterile CompoundingOutsourcing Facility |
| **License Expiration Date** | 2/28/2025 |
| **License Original Issue Date** | 11/10/2021 |
| **Address of Record** | 15215 TECHNOLOGY DR<br>BROOKSVILLE, FL 34604 |
| **Discipline on File** | No |
| **Public Complaint** | No |

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

# 10D

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440

## APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New OUTSOURCING FACILITY
☑ Ownership Change (Provide current license number if making changes:) OUT 00016
☐ 503a OR ☐ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1-3 & 4
☐ Non Publicly Traded Corporation – Pages 1-3 & 5
☑ Partnership - Pages 1-3 & 6
☐ Sole Owner – Pages 1-3 & 7

**GENERAL INFORMATION to be completed by all types of ownership**

Facility Name: STERRX, LLC

Physical Address: 141 Idaho Avenue

City: Plattsburgh State: NY Zip Code: 12903

Telephone: 1-518-324-7879 Fax: 1-518-324-7880

Toll Free Number: 1-800-927-9800 (Required per NAC 639.708)

E-mail: thomas.dominy@sterrx.com Website: WWW.STERRX.COM

Supervising Pharmacist: THOMAS J. DOMINEY Nevada License #: 22803

**SERVICES PROVIDED**

Yes/No

☐ ☑ Parenteral
☑ ☐ Sterile Compounding
☐ ☑ Non Sterile Compounding
☐ ☑ Mail Service Sterile Compounding
☐ ☑ Other Services: _____

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only Date Processed: _____ Amount: 500.00 CK - 89905

3.22.23

**APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY** **Page 2**

FEI Number (From FDA application): 30-10840309

Please provide the name of the facility as registered with the FDA and the registration number:
SterRx, LLC

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
N/A

Please provide the name and Nevada license number of the supervising pharmacist:
Name: THOMAS J. DOMINY Nevada License Number: 22803

A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: N/A

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

## APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☑

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Jerry C. Webb
Print Name of Authorized Person

13 March 2023
Date

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY Page 6

**OWNERSHIP IS A PARTNERSHIP** General _____ Limited X

Partnership Name: SterRx, LLC

Mailing Address: 141 Idaho Avenue

City: Plattsburgh State: New York Zip Code: 12903

Telephone Number: 1-518-324-7879 Fax Number: 1-518-324-7880

Contact Person: Jerry C. Webb, EVP Operations

List each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership
Use separate sheet if necessary

| Name | G or L | Percentage |
|---|---|---|
| Please see attached. | | |
| | | |

List names of 4 largest partners and percentage of ownership:

Name: Please see attached. %: _____

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

List any physician shareholders and percentage of ownership.

Name: No %: _____

Name: _____ %: _____

Name: _____ %: _____

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

- Please provide a thorough response to the questions below and provide any necessary supporting documents.
- For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
- For an existing pharmacy, send the completed form to the address indicated above.

### Section 1: General Information

Pharmacy Name: STERRX, LLC

NV Pharmacy or Outsourcing facility license # (if applicable): OUT00016

Physical Address: 141 IDAHO ROAD

City: PLATTSBURGH State: NY Zip: 12903

Mailing Address (if different from physical address): AS ABOVE

City: State: Zip:

Telephone: 1--518-324-7879 Toll Free # (NAC 639.708, NRS 639.23286):

Fax: 1-518-324-7880 Contact Email: JWEBB@SAGENTPHARMA.COM

Website: WWW.STERRX.COM

Nevada Business License # (if applicable) OUT00016

Supervising/Managing Pharmacist Name (NRS 639.220): THOMAS DOMINY

Supervising/Managing Pharmacist NV Pharmacist Registration #: 22803

Name of Person with direct knowledge of compounding procedures: THOMAS DOMINY

Email of Person with direct knowledge of compounding procedures: thomas.dominy@sterrx.com

Telephone of Person with direct knowledge of compounding procedures: 1-518-324-7879

**Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)**

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☐ Low ☐ Medium ☒ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☒ Yes ☐ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Norepinephrine in 0.9% NaCl
Phenylephrine in 0.9% NaCl
Epinephrine in 0.9% NaCl
Diltiazem in 0.7% NaCl and 5% Dextrose
Fentanyl in 0.9% NaCl
Hydromorphone in 0.9% NaCl
Ketamine in 0.9% NaCl

All products contain various strengths. All packaged via automation in a traditional IV bag or Blow-Fill-Seal bottle (BFS).

4. Will you be utilizing beyond use dates in excess of USP-797? ☒ Yes ☐ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:

Stability program created to establish expiry dating for all products. Each product line undergoes real time and accelerated stability and sterility testing. Data collected and analyzed to determine expiry dating not BUD. SOP-VAL-0097, Stability Program, governs this process.

6. What laboratory performs this additional testing?

Name: ARL Bio Pharma

Address: 840 Research Pkwy #546

City: Oklahoma City State: OK Zip: 73104

Telephone: (405) 271-1144

7. What is your procedure for visual inspection of compounded sterile products?

SOP-P-0401, Visual Inspection of Injectable Products. This procedure covers sterile injectables manufactured on any of the Blow, Fill, Seal (BFS) Machine and IV Bag Fill and Seal Machines. This inspection utilizing an approved light source will take place before any subsequent packaging operations are performed. All personnel performing visual inspection are certified by testing prior to being put on the inspection line.

8. How often do you perform glove fingertip and medial fill testing?

Glove fingertip qualifications of personnel involved in sterile processing are performed annually.
Medial Fill testing of equipment is performed semiannually, with qualification of personnel required annually.

9. What is your policy if an employee fails a glove fingertip or media-fill test?

Glove fingertip - Each occurrence is investigated internally for root cause and impact to compounded lot. Trend of 3 failures leads to revocation of participation in processing, pending formal retraining and qualification/testing.

Media-fill failure - results in investigation of root cause and denial of qualification until a successful media fill is performed.

10. Describe your initial and annual training program for all personnel performing sterile compounding:

The following training must be completed prior to an operator participating in sterile processing activities.

- Aseptic Processing Training Using Barrier Technology - Blow Fill Seal Machine / Bausch Robotic Bag Filler
- The Importance of Aseptic Practice in Pharmaceutical Manufacturing
- Aseptic Refresher Training
- Successful testing in 3 glove fingertip and sleeve tests
-Successful participation in media fill test

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Each area of processing is governed by SOP for cleaning procedures relating to batch processing, daily, and weekly cleaning requirements.

Daily - All surfaces, floors, interior of pass through boxes, and equipment used.
Weekly - Ceilings, walls, doors, vents, floor, exterior surfaces of RABS, and compressed air ports.

Cleaning/Disinfectant Agents
Sterile 70% IPA
Sterile MINNCARE
CANI HI-Con 256
Sterile Paradox RTU

12. Who performs the sterile compounding process at your facility?

Compounding of raw materials is performed by a Pharmacist and a Production Operator in an ISO 7 compounding suite.

Filling of the compounded solution is performed via automated technology. The "fill zone" of all automated equipment is maintained and monitored as an ISO 5 area.

13. Who is responsible and accountable for the sterile compounding process at your facility?

Pharmacists are responsible and accountable for the compounding process.

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

Shipping studies have been performed on all products using our currier service FedEx with their standard shipping conditions in the summer and winter seasons. Through the shipping studies, the products then undergo stability testing to ensure that the conditions have not effected the safety and efficacy of the product. SOP-QA-0032, Shipping Studies, govern this process.

| Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.) | | |
|---|---|---|
| 1. What type of primary engineering controls will you be using in your facility?<br>RABS are the primary engineering control of all automated technology used in the filling process of compounded products at SterRx. | | |
| 2. Is your BSC or CACI vented 100% to the outside? | ☐ Yes | ▣ No |
| 3. Do you have a negative pressure buffer room at your facility? | ☐ Yes | ▣ No |
| 4. Will you be compounding with antineoplastic HDs or HD API? | ☐ Yes | ▣ No |
| 5. If yes, are the drugs stored in an externally ventilated, negative pressure room? | ☐ Yes | ☐ No |
| 6. Will you be utilizing a closed system transfer device? | ☐ Yes | ▣ No |
| 7. If yes, list the name of the device:<br>N/A | | |
| 8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?<br>Standard storage conditions are listed on the label of each product as required by Section 503B of the DQSA. | | |
| 9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?<br>N/A - Facility does not compound hazardous drugs. | | |

**Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)**

1. List the specific high risk sterile products that your facility compounds:

Norepinephrine in 0.9% NaCl
Phenylephrine in 0.9% NaCl
Epinephrine in 0.9% NaCl
Diltiazem in 0.7% NaCl and 5% Dextrose
Fentanyl in 0.9% NaCl
Hydromorphone in 0.9% NaCl
Ketamine in 0.9% NaCl

All products contain various strengths. All packaged via automation in a traditional IV bag or Blow-Fill-Seal bottle (BFS).

2. What sterilization methods are utilized at your facility?

Membrane filtration using a 0.2 micron filter.

3. Does your facility utilize biological indicators? ☐ Yes ☒ No

4. If yes, describe how they are utilized:

N/A

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dr. Thomas J. Dominy, PharmD, BCSCP

Name of Person who Completed the Form

Sr. Pharmacy Manager

Title

Thomas J. Dominy Digitally signed by Thomas J. Dominy Date: 2023.04.19 10:19:22 -04'00'

Signature (copies or stamps not accepted)

19 Apr 2023

Date

| Board Use Only | Date Received: _____ Date Approved: _____ Approved By: _____ |
|---|---|

SterRx® STERILE MANUFACTURER OF 503B COMPOUNDED DRUGS

**SterRx, LLC**
141 IDAHO AVENUE
PLATTSBURGH, NY 12903
844.319.7799

March 2, 2023

To Whom it May Concern:

Subject: Change of Ownership: SterRx, LLC

Please be notified that a 100% change in stock ownership, at a grandparent level, will be in effect at the following facility as of February 28, 2023:

SterRx, LLC
141 Idaho Avenue, Plattsburgh, NY 12903

Owners to be removed: Nichi-Iko Pharmaceutical Co, Ltd.
Sagent Pharmaceuticals, Inc.

New Owner: Que Pharma Inc.
251 Little Falls Drive
Wilmington, DE 19808

Please see the enclosed pre- and post-closing organizational chart.
**SterRx, LLC's management team will remain the same:**

Jerry Webb, EVP Operations
Sagent Pharmaceuticals
[redacted] N. Roselle Rd., #450
Schaumburg, IL 60195
ph: 1-[redacted]

Sarah McCoy, Director Plant Ops
SterRx, LLC
[redacted] Idaho Ave
Plattsburgh, NY 12903
ph: 1-[redacted]

Thomas Dominy, PIC
SterRx, LLC
[redacted] Idaho Ave
Plattsburgh, NY 12903
ph: 1-[redacted]

SterRx's day-to-day operations will remain uninterrupted, continuing 'business as usual', under the same:

Federal Tax Identification Number: 61-1718460
DUNS Number: 049167014
FDA Establishment Number: 30-10840309
DEA Registration Number: RS0547591

Should additional information regarding this Change of Ownership, at the grandparent level, or any other questions regarding SterRx, LLC, please do not hesitate to contact us.

Sincerely,

DocuSigned by:
Jerry Webb
C5A8DD8908E349F...

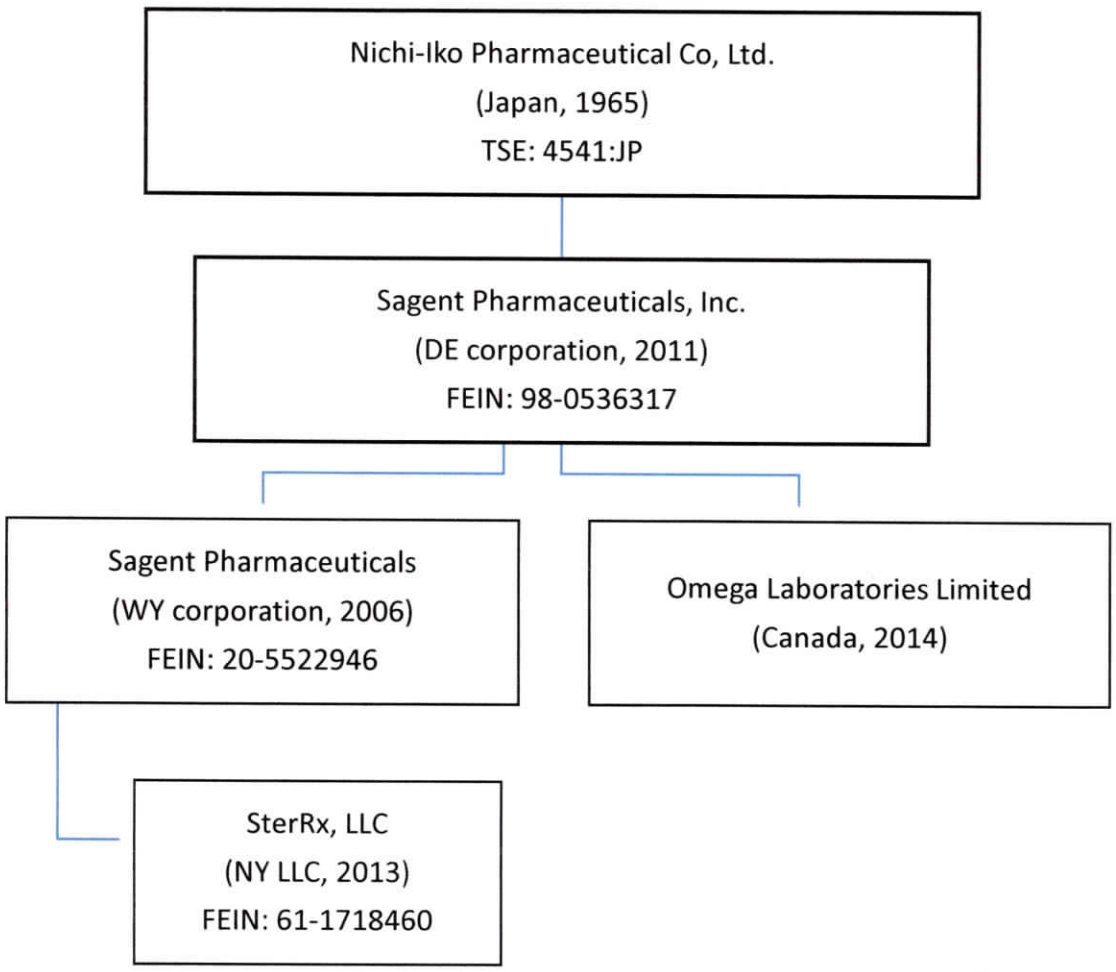
Jerry Webb
Sagent Pharmaceuticals

SterRx® STERILE MANUFACTURER OF 503B COMPOUNDED DRUGS

SterRx, LLC
141 IDAHO AVENUE
PLATTSBURGH, NY 12903
844.319.7799

# SterRx, LLC
# 2023 Change of Ownership
effective Closing Date: February 28, 2023

## PRE-CLOSING LEGAL STRUCTURE



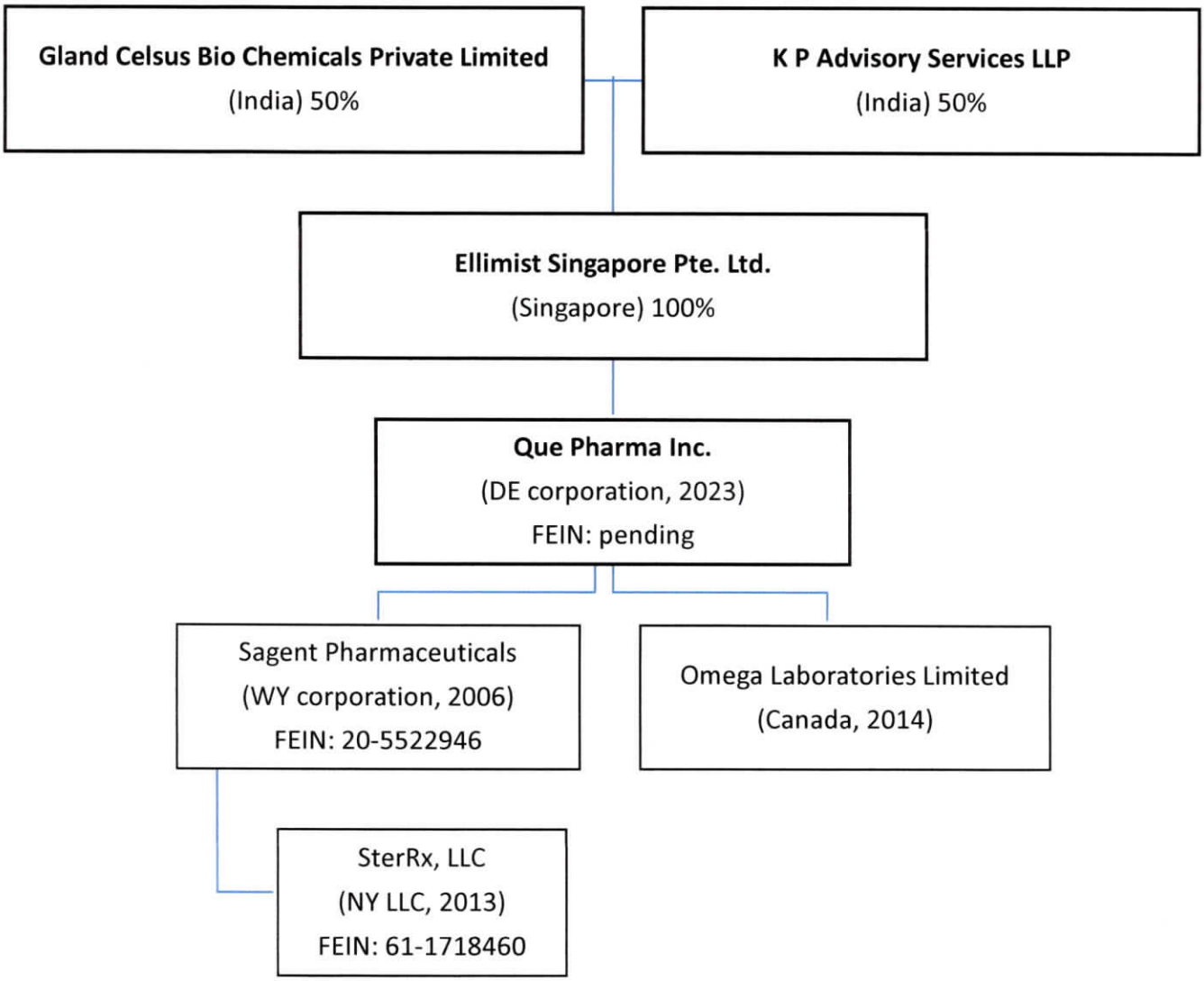

March 2, 2023

SterRx® STERILE MANUFACTURER OF 503B COMPOUNDED DRUGS

SterRx, LLC
141 IDAHO AVENUE
PLATTSBURGH, NY 12903
844.319.7799

# SterRx, LLC
# 2023 Change of Ownership
effective Closing Date: February 28, 2023

## POST-CLOSING LEGAL STRUCTURE




March 2, 2023

2877

# SterRx, LLC - Capitalization Table – February 28, 2023

Organized in the State of New York

Federal Tax ID #: 61-171-8460

| | Pre-Closing | | | | Post-Closing | | | |
|---|---|---|---|---|---|---|---|---|
| **Unitholder** | **Common Units** | **Series A Preferred Units** | **Total** | **% FD** | **Common Units** | **Series A Preferred Units** | **Total** | **% FD** |
| Carl Martin | 0 | 882,353 | 882,353 | 5.6% | 0 | 882,353 | 882,353 | 5.6% |
| Kent Smeltz | 0 | 882,353 | 882,353 | 5.6% | 0 | 882,353 | 882,353 | 5.6% |
| Sagent Pharmaceuticals, Inc. | 6,058,250 | 3,921,569 | 9,979,819 | **72.1%** | 7,398,013 | 3,921,569 | 11,319,582 | **72.1%** |
| Timothy J. Miller | 100,000 | 0 | 100,000 | 0.6% | 100,000 | 0 | 100,000 | 0.6% |
| Justin L. Miller | 7,500 | 0 | 7,500 | 0.0% | 7,500 | 0 | 7,500 | 0.0% |
| Charles M. Kaulfuss itf Sandra Hawkins | 25,000 | 0 | 25,000 | 0.1% | 25,000 | 0 | 25,000 | 0.1% |
| Sandra Hawkins itf Charles M. Kaulfuss | 694,375 | 0 | 694,375 | 4.4% | 694,375 | 0 | 694,375 | 4.4% |
| Denis G. LaVigne & Dawn LaVigne | 170,700 | 0 | 170,700 | 1.1% | 170,700 | 0 | 170,700 | 1.1% |
| James McKee III | 475,000 | 0 | 475,000 | 3.0% | 475,000 | 0 | 475,000 | 3.0% |
| Next Generation Trust Services fbo Mary M. McKee | 475,000 | 0 | 475,000 | 3.0% | 475,000 | 0 | 475,000 | 3.0% |
| Jeff LaBombard | 500,000 | 0 | 500,000 | 3.2% | 500,000 | 0 | 500,000 | 3.2% |
| Winslow Moore and Vera Delorme | 154,412 | 0 | 154,412 | 1.0% | 154,411 | 0 | 154,412 | 1.0% |
| **TOTAL** | **10,000,000** | **5,686,275** | **15,686,275** | | **10,000,000** | **5,686,275** | **15,686,275** | |

*Note: percentages do not add to precisely 100.0% due to rounding

SterRx, LLC is 72.1% owned by Sagent Pharmaceuticals.
Sagent Pharmaceuticals is wholly owned by **Que Pharma, Inc.**

**STATE OF NEW YORK**

**DEPARTMENT OF STATE**

**Certificate of Status**

I, ROBERT J. RODRIGUEZ, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

| | |
|---|---|
| **Entity Name:** | STERRX, LLC |
| **DOS ID Number:** | 4445915 |
| **Entity Type:** | DOMESTIC LIMITED LIABILITY COMPANY |
| **Entity Status:** | EXISTING |
| **Date of Initial Filing with DOS:** | 08/15/2013 |
| **Statement Status:** | CURRENT |
| **Statement Due Date:** | 08/31/2021 |

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on June 23, 2022 at 01:43 P.M.

ROBERT J. RODRIGUEZ, Secretary of State

Brendan C. Hughes

By Brendan C. Hughes
Executive Deputy Secretary of State

Authentication Number: 100001768273 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

2879

# THE UNIVERSITY OF THE STATE OF NEW YORK
# EDUCATION DEPARTMENT

## NEW YORK STATE BOARD OF PHARMACY

2022-25

NAME OF SUPERVISOR
THOMAS DOMINY

THIS IS TO CERTIFY

STERRX, LLC
141 IDAHO AVENUE
PLATTSBURGH, NY 12903

is duly recorded as a

## REGISTERED OUTSOURCING FACILITY

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE FIRST DAY OF MARCH, 2022.
THIS CERTIFICATE EXPIRES ON THE TWENTY-EIGHTH DAY OF FEBRUARY, 2025.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER
034102

EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

THE STATE EDUCATION DEPARTMENT/THE UNIVERSITY OF THE STATE OF NEW YORK/ALBANY, NY 12234

NEW YORK STATE BOARD OF PHARMACY, Kimberly Leonard, Executive Secretary
89 Washington Avenue, 2nd Floor, Albany, NY 12234-1000
Tel. (518) 474-3817, ext. 130; Fax (518) 473-6995
E-mail: pharmbd@nysed.gov ; Web: www.op.nysed.gov

August 22, 2017

**Verification of an In State or Nonresident Pharmacy, Manufacturer/Repacker/Wholesaler or individuals Licensed in New York:**

Online verification of the registration status of an in State or Nonresident pharmacy, and/or manufacturer/repacker/wholesaler, as well as the license and registration status of licensed professionals, can be performed free of charge at http://www.op.nysed.gov/opsearches.htm. An additional search can be performed on each verification screen to determine if an establishment or licensee has been disciplined by this Department.

Note: No other form of verification is available for pharmacy establishments. Please do not use "request for Written Confirmation of New York State Licensure" for verification of a registered establishment; that form is used only for certification or verification of licensed individuals.

**Verification of Licensed Professionals (not establishments):**

The Board Office cannot provide letters of good standing or license verification; however, the Certification/Verification Unit can provide documentation that will likely meet your needs.

A form must be submitted with the appropriate fee for either a certification or verification of a license. The difference between certification and verification is explained on the form which is available at http://www.op.nysed.gov/documents/confirmoflic.pdf.

I hope this information is helpful.

Thank you.

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| RS0547591 | 02-29-2024 | $3699 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,3,3N, 4,L1 | MANUFACTURER | 02-28-2023 |

STERRX LLC
141 IDAHO AVE
PLATTSBURGH, NY 129033987

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

**THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.**

**CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE**
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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141 IDAHO AVE
PLATTSBURGH, NY 129033987

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Form DEA-223 (9/2016)

# Nevada State Board Of Pharmacy

(Licensee mailing address for window envelope)

THIS STUB IS YOUR RECEIPT

Date: 05/16/2022
Amount:
License #: 22803

Thomas J. Dominy

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Pharmacist
Effective Date:05/16/2022
Expires:10/31/2023

Thomas J. Dominy

License #
22803
Active

IDENTIFICATION ONLY
DOES NOT MEET POSTING REQUIREMENTS

Trim ID Card to fit your wallet

---

License Type: Pharmacist
License #: 22803
Effective Date:05/16/2022

NEVADA
**STATE BOARD OF PHARMACY**
**Pharmacist**

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENSED

Expires: 10/31/2023
STATUS: Active

Thomas J. Dominy

**NONTRANSFERABLE**

POST THIS LICENSE PROMINENTLY IN A CONSPICUOUS PLACE

THE UNIVERSITY OF THE STATE OF NEW YORK
THE STATE EDUCATION DEPARTMENT
OFFICE OF PROFESSIONAL DISCIPLINE

# PHARMACY INSPECTION REPORT ☐ Pharmacy ☐ M/W 503B ✓

Inspection # A3742 + A3743 conducted by
Investigator Kelly Sullivan
Date 9/21/2021 10/12/21 11/4/21 Time In/Out ____ / ____

(1) Routine
2. New Registration
3. Transfer Ownership
4. Discontinuance
5. Change of Name/Address
(6) Medication Recall
7. Complaint Related
8. Follow-up to Previous Inspection
9. Special Project or Renovation

Reg. name SterRx, LLC
Trade name ____
No. and Street 141 Idaho Ave
City Plattsburgh County Clinton Zip 12903
Reg. # 034102 Telephone (518) 324-7879
Hours open per week 120 # RXs daily ____

| Pharmacists' Names | Hrs. Per Week | License Number | License Date | License Displayed | Registration Displayed |
|---|---|---|---|---|---|
| S.P. Sue E. Martin | 40 | 035182 | 3/25/1983 | (Y) N | (Y) N |
| Pharm. Thomas Dominy | 40 | 056883 | 7/12/12 | (Y) N | (Y) N |
| Pharm. Courtney Gilmore | 40 | 067080 | 2/5/2021 | (Y) N | (Y) N |
| Pharm. David G. Waczkowski | 40 | 063359 | 8/28/2017 | (Y) N | (Y) N |
| Pharm. Kessing, Rosanna (not present day 1) | 40 | 0580616 | 7/10/2013 | (Y) N | (Y) N |
| Intern | | | | Y N | Y N |

Circle "S" if item is Satisfactory. Circle "N" if item is Not Satisfactory, and explain in Details of Inspection section below. Be sure to include item number in explanation.

1. Registration name on exterior ..... (S) N
2. Licenses/current reg. displayed ..... (S) N
3. Registered pharmacist on duty ..... (S) N
4. Equip., facilities, and ref. items ..... S (N)
5. Price list available/current ..... S N/A
6. Drug stock current ..... S (N)
7. Stock properly branded ..... S (N)
8. Daily RX record ..... S N/A
9. Required RX filings ..... S N/A
10. DEA records complete/available ..... (S) N
11. Safety/approp. closures/containers ..... S N/A
12. RX labels required information ..... (S) N
13. Valid RX formats ..... S N/A
14. Substitution law compliance ..... S N/A
15. Required information on RXs ..... S N/A
16. Refill authorization/fill ..... S N/A
17. Refills in daily record ..... S N/A
18. Controlled substance compliance ..... (S) N
19. General sanitation ..... S (N)
20. Intern/unlicensed supervision ..... S (N)
21. Counseling offered/given/refusals documented ... S N/A
22. Types of pharmacy (circle those applicable): retail, hospital, skilled nursing, assisted living, (compounding) (sterile preparation) internet, home delivery, mail delivery, nuclear, veterinary (503B)

**Details of Inspection** On 9/21/21, 10/12/21 and 11/4/21 I accompanied Edmund Mrak, FDA Investigator and Lori Newman, Investigator on an FDA inspection of SterRx, LLC. On August 10, 2021, SterRx LLC announced the voluntary recall of 3 lots of Sodium Bicarbonate in 5% Dextrose Injection 150 mEq per 1,000 ml due to water borne microbial contamination. The recall was initiated at the hospital level. The FDA contacted the Pharmacy

**Recommendation (completed in office)**
Investigator ____
Supervisor ____

I have received a copy of this inspection report.
Signature ____
Print name ____
Title ____ Date ____

THE UNIVERSITY OF THE STATE OF NEW YORK
THE STATE EDUCATION DEPARTMENT
OFFICE OF PROFESSIONAL DISCIPLINE

## PHARMACY INSPECTION REPORT

Inspection # Conducted by
Investigator Kelly Sullivan
Date 9/21/21, 10/6/21 & 11/4/21 Time

Reg. name SterRx, LLC
Trade name
No. and Street 141 Idaho Ave

Details of Inspection Board Office to invite an ~~rep~~ investigator on this inspection. On 10/4/21, SterRx shut down all compounding operations. The last product shipped interstate were

① 4mg Norepinephrine in 0.9% Sodium Chloride Injection 250ml (16 mcg/ml) BFS IV bag

② 160 mg Norepinephrine in 0.9% Sodium Chloride Injection 250ml (64 mcg/ml) BFS IV Bag both on 10/1/21 SEE 211-Shipment information for 52/438.pdf Shipment details the product received in Little Rock, AK on 10/5/21. Subsequently, on 11/10/21 SterRx announced the voluntary recall of approximately 240 lots within their expiry period due to equipment and process issues that could lead to a lack of sterility assurance for products intended to be sterile. The recall is to the hospital pharmacy level. To date, there were no product complaints or adverse events associated with these lots. received

SterRx employees present on the first day were:
Sarah McCoy, Director-Plant Operations
Tracy M. Roth, Acting Site Quality Manager
Tony Pilcher, Director - R&D
Michael Hitchingham, Director, Quality Operations, Sagent Pharmaceuticals
Napoleon Harrington, Associate Director of Production
Jennifer Garrant, Administrative Assistant, QA.
Sue Martin, Supervising Pharmacist.
In addition to the above list is an attached employee list. Checks indicate the employee worked that day.
Potential issues are indicated below.

① Receiving area was dirty and dead bugs were found at receiving dock area. Receiving process does not include cleaning of received goods prior to taking them into the warehouse. See photos (1-43) and SOP-SC-002T (SOP PHR 202)

② In the non-GMP labeled location O2C2 refrigerator ~~the~~ contained food and a package wrapped in plastic labeled ATCC organism.

Recommendation (completed in office)
Investigator _____
Supervisor

I have received a copy of this inspection report.
Signature
Print name
Title Date

THE UNIVERSITY OF THE STATE OF NEW YORK
THE STATE EDUCATION DEPARTMENT
OFFICE OF PROFESSIONAL DISCIPLINE

## PHARMACY INSPECTION REPORT

Inspection # Conducted by
Investigator Kelly Sullivan
Date 9/21/21, 10/12/21 & 11/4/21 Time _____

Reg. name SterRx, LLC
Trade name
No. and Street 141 Idaho Ave

Details of Inspection See Photos (5, 7-8). Philip Hewitt, Materials Management Supervisor stated that he did not know the reason for this.

(3) Location 02K2 had filters, both quarantined and released in the same area. Philip Hewitt stated this area is being enlarged because they need more area for filters. See photos 11.

(4) The area above the filters, 02K2 had adhesive stored there. See photo 9. It was GMP and non-GMP on top of each other.

(5) Locations 12ZA1 and 11ZA1 contain the back-up samples for sterility testing. A TempTale Vitra monitoring device was attached to the shelving. McCoy stated that this type of device is used throughout the facility. The readings are downloaded weekly. I asked why this was not done more often. McCoy said they've done studies to show how the warehouse temperature fluctuates, so there is no need. Later, I discussed this with Ed Mrak if that was acceptable and shouldn't it be done at a minimum of every shift to which he agreed. An email is sent when temperature goes out of range to materials management, engineering/maintenance, quality assurance, quality control and pharmacy. See ~~SOP-SL-0037~~ SOP does not match with what McCoy stated as the process. 33-SOP WRH 107 (SOP-SL-0031.

(6) In location 12ZA1, 28 (twenty-~~eight~~) documents of master batch records (MBRs) that were old MBRs were found sitting in this location. Roth stated their new computer system (VIVA - was told) applied an expiration date of 3 days from the date of printing and applies that date to the tangible record at the bottom of the page. None of these documents had any date on the bottom, so they were said to be old MBRs. They should have been destroyed ~~to~~ to minimize the risk of using these to compound. See 36-Retention MBR pages.

(7) The hot pack oven used as the dry heat sterilizer ~~had~~ was outdated (SOP Aug 21) release stickers. They should have been removed (destroyed) almost a month ago. See Photo 14

(8) Inside a stability chamber there was a box labeled ~~Hemoglobin~~

Recommendation (completed in office)

Investigator _____

Supervisor

I have received a copy of this inspection report.

Signature

Print name

Title

Date

THE UNIVERSITY OF THE STATE OF NEW YORK
THE STATE EDUCATION DEPARTMENT
OFFICE OF PROFESSIONAL DISCIPLINE

PHARMACY INSPECTION REPORT

Inspection # Conducted by
Investigator Kelly Sullivan
Date 9/21/21, 10/12/21 & 11/4/21 Time

Reg. name SterRx LLC
Trade name
No. and Street 141 Idaho Ave

Details of Inspection 16mg Norepinephrine in 5% Dextrose Injection. Found inside the box were: See ~~SterRx19.jpg~~ KW AND ~~SterRx19.jpg~~ AND SterRx22.jpg

(a) Nine bags of Diltiazem 125mg/125ml in 0.7% Sodium Chloride Injection Lot # BOC, Expires 11/30/20, compounded 6/3/2020.

(b) Four bags of Norepinephrine 4mg/250ml in 5% Dextrose Injection, Lot # AQP, expiration 9/20/20, compounded 9/26/2019

(c) Four bags of Norepinephrine 8mg/250ml in 5% Dextrose Injection, Lot # BAW, Exp 10/17/2020, compounded 4/20/20 See SterRx20.jpg

(d) Four bags of Norepinephrine 16mg/250ml 5% Dextrose Injection, Lot # BEL, expires 9/8/20, compounded 3/12/20. See SterRx23.jpg

(9) Operators (unlicensed employees) are compounding in a 503B facility. McCoy stated that a pharmacist is present during compounding (the tank rooms) with the operator (unlicensed employee) that gets the tank ready. The pharmacist tells the operator (unlicensed employee) when they may start the process. S21356 MSD I witnessed this and confirmed with

(b) Also, there is a pharmacist in the packaging room and the operator Sarah McCoy lines up the empty "sterile" bags in the RABS and waits for the pharmacist to give the go ahead to proceed. I witnessed this and confirmed with McCoy

(c) Acceptable quality level (AQL) checks in the packaging area are performed by a lead operator (unlicensed employee). S19049 TD Baillargeon S19115 F. Lafountain

(10) Employees work in street clothes in packaging areas due to COVID supply issues. McCoy stated employees may work in clean street clothes because of the COVID supply issues. ~~SEE~~ KW McCoy said employees have the option to change into scrubs after arriving at the facility. In the packaging room everyone wore street clothes, except for one employee.
See 55-CC-2020-043, for rooms 140, 144, 143, 302 ↓ 21 CFR 211.42(c)(10)

(11) Aseptic Processing areas are deficient with air supply that is filtered through high-efficiency air filters under positive pressure (iii) See FDA 483 - (a) Blow-Fill-Seal (BFS) operations in the open parison process. Observation 1.

Recommendation (completed in office)
Investigator
Supervisor

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## PHARMACY INSPECTION REPORT

Inspection # Conducted by
Investigator Kelly Sullivan
Date 9/21/21, 10/12/21 & 11/4/21 Time

Reg. name SterRx, LLC
Trade name
No. and Street 141 Idaho Ave.

Details of Inspection are conducted under air that is less than ISO5. BFS 172, Equipment #E0201 and BFS 321-190, equipment #E0581 are ISO-7 in the cutting and shuttling of the parison process. In addition, the airflow pattern and airborne particulates in the critical processing zones during operation of BFS 172 and BFS 321-190 where parisons are cut and the open parisons are shuttled to the point of aseptic filling has not been evaluated. SEE 57- One Source Environmental RPT 10-28-2021/1120-Final-Report 1. & Parison 321-1.mp4 & Parison 321-2.mp4

(b) Design & construction of the IV Bag-filling line, Equipment #E0432 Bausch Type 529 and its enclosure do not provide first pass HEPA-filtered laminar flow air over all critical areas within the ISO5 area as follow:

(i) ~~PR-2018-187-E0432-55.docx~~ RPT-2018-187-E0432-55, Bausch Type 529 Bag Filling and Sealing Machine (E0432) Smoke Study, identified turbulence & upward flow of air near Fill Station #1. This was accepted & approved by firm management without attempting corrective actions.

(ii) First pass air flow (HEPA-filtered) laminar flow air is ~~not provide~~ blocked by the "plenum" (metal bended sheet) over approximately one-half of the vibratory bowl and the track system to convey sterile closures (ports) to the filling side of the Bausch Type 529 Bag Filling & Sealing Machine. Also, the above mentioned smoke study did not evaluate the airflow pattern in the area of the vibratory bowl.

(iii) First pass HEPA-filtered laminar flow air is not provided over the filling side of the Bausch Type 529 Bag Filling & Sealing Machine where open IV Bags are manually removed from wrapping and exposed, held and passed to the filling section of the line.

(c) First pass HEPA Filtered air is obstructed by the glove port and glove and the vibratory bowl over open, partial bags of syringe plungers held

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PHARMACY INSPECTION REPORT

Inspection # Conducted by
Investigator Kelly Sullivan
Date 9/21/21 & 10/12/21 Time 11/4/21

Reg. name SterRx, LLC
Trade name
No. and Street 141 Idaho Ave

Details of Inspection adjacent to the vibratory bowl used to hold and convey plungers on the aseptic syringe filling system, Inova SV-122 Automatic Syringe Filling and Sealing Machine with RABS Equipment #E0433. Also, the syringes ~~were~~ are removed from the E0433 and exposed to less than ISO 5 air. See SLE0433-Filled Nest Remove Empty Nest Added SLE0433 In Pass-Thru Exterior

(12) Refer to Observation 2 of the FDA ~~483~~ KU Form 483 and 21CFR 211.94(b) Container closure systems do not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.

(a) See Packaging - Copper Room.pdf and ~~Blend~~ KU BFS Compounding-Filling - Cap and bag ~~are~~ interfacing surfaces and the interstitial space making up the container closure of BFS IV bags containing drug products produced in BFS 172, #E0201 are not kept sterile. Filled BFS IV bags are manually offloaded from a conveyer to be held in an ISO 7 area before capping. The capping process includes sanitization of the BFS IV bags with non-sterile 3% Hydrogen Peroxide solution, UV light exposure and drying with filtered ~~air~~ KU followed by passage under heated air from a "heat gun" that is particle generating by design (brushed blower motor) before capping under ISO 7 conditions.

SEE 1310-Sanitization tunnel photo.pdf

(b) See EM.pdf
BFS IV bags containing drug products produced in BFS321-190 are conveyed and capped in-line under ISO-7 conditions

(13) Refer to Observation 3 in FDA Form 483 and 21CFR 211.42(c)(10)(iv) Surface and airborne viable monitoring program for aseptic filling operations is not designed and conducted to provide meaningful data to support the quality of the drug products intended to

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Investigator _____
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PHARMACY INSPECTION REPORT

Inspection # Conducted by
Investigator Kelly Sullivan
Date 9/21/21, 10/14/21, 11/4/21 Time

Reg. name SterRx LLC
Trade name
No. and Street 141 Idaho Ave

Details of Inspection be sterile. The procedure allows surface and air samples from within ISO-5 environments to yield microbiological containments of 1 colony forming unit (CFU) without conducting an investigation.

(a) Prior to 8/2021 environmental monitoring (EM) permitted >1 CFU with no investigation or other action and batches were released.

(i) For #E0432, See Packaging S21066, Compounding - Filling S21066, Environmental ~~Se~~ ~~S21066~~ ~~Bat~~ # Monitoring S21066 and QA Product Release S21066 ~~Bat~~ Packaged as Lot# BQB and released on 5/7/2021, Exp 11/19/2021

(ii) For #E0433 EM S20141
See ~~Syring Filling~~ ~~S20141~~ and QA Product Release S20141 Lot AZX.pdf
Packaged as lot#AZX and released 5/20/2020, expiration date 7/5/2020.

(iii) For #E0581
See Environmental Monitoring S21185 and QA Product Release S21185
Packaged as Lot# BUP, Released 5/21/2021, Expiration: 12/9/2021.

(iv) For #E0201
See EMS20022.pdf and QA Product Release S20022
Packaged as Lot # AVA, Released: 4/9/2020, Expiration: 8/22/2020

(b) Environmental (current) monitoring plans and specifications for airborne and surface viable monitoring permit 1 CFU recoveries within the ISO 5 classified zones inside the enclosures of the #E0432 and #E0433 without requirements for investigation and action.

(i) See 78-WI-MCB-0017 EM Bag Filler
(1) SEE ~~EM~~ Environmental Monitoring S21160 and QA Product Release S21160.
Packaged as Lot# BTR, Released 5/7/2021 Expiration Date 12/2/2021.
(2) See EM 20171 and QA Product Release S20171.
Packaged as Lot BBB, Released 5/13/2020, Expiration 3/18/2021.

(ii) See 78-WI-MCB-0012 EM syringe line Allows drug products on the syringe line

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Inspection # Conducted by
Investigator Kelly Sullivan
Date 9/21/21, 10/12/21, 11/4/21 Time

Reg. name SterRx LLC
Trade name
No. and Street 141 Idaho Ave

Details of Inspection #E0433 permits surface and air samples from within the ISO 5 environment to yield microbiological contaminents of 1CFU without investigation and action.

(a) 1CFU allowed in the critical filling zones of BFS 172, #E0201 and BFS 321-190, #E0581 without requirements for investigation and action ← See EM-1508 Cleanroom.pdf

(i) See WI-MCB-0009 for drug products filled on BFS172, #E0201

(1.) See: Environmental Monitoring S21159
QA Product Release S21159
S21159 Packaged as Lot: BTQ and released 4/30/2021, Expiration: 1/30/2022

(ii) See WI-MCB-0011 for drug products filled on BFS 321-190, #E0581 See EM-1507 Cleanroom with Sanitization Traxel and Capper.pdf

(1.) See: EMS21061
QA Checklist S21061
S21061 Packaged as Lot: BPW, Released: 2/23/2021, Expiration Date 12/28/2021.

(2) Airborne particle monitoring program for aseptic filling operations is not designed and conducted to provide meaningful data to support the quality of drugs products intended to be sterile. You do not monitor airborne particulates to ISO 5 classifications in all critical locations; frequency of airborne particulate monitoring is not adequately supported; and the orientation of particle counter probes is not directed into the flow of air in monitored locations.

(a) IV Bag filling line, #E0432

(i) Airborne particulates in close proximity to open IV bags that are manually unwrapped and held for filling are not monitored.

(ii) There is no scientific justification for the frequency of airborne particulate monitoring performed on the filter sites and

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Investigator Kelly Sullivan
Date 9/21/21, 10/12/21 & 11/4/21 Time

Reg. name SterRx LLC
Trade name
No. and Street 141 Idaho Ave

Details of Inspection the injection port feed side pre-batch filling, once per shift during filling, and post filling operation according to KR-WI-MCB-0017EM,

(iii) Orientation of the particle counter probes is not directed into the flow of air in monitored locations near the filler bag filler and the port bowl and track.

Also, WI-MCB-0017 and batch monitoring records during the filling of these below do not meet ISO5 classification

See 78-WI-MCB-0017EM bag filler

- 150 mEq Sodium Bicarbonate in 5% Dextrose Injection:
  0.5 µm Alert ≥ 4600 particles/ft³
  0.5µm Action ≥ 485 particles/ft³
- ~~125 mEq KCl~~
- 125 mg Diltiazem D5W/125 Diltiazem 0.7% Sodium Chloride Injection:
  0.5µm Alert ≥ 5460 particles/ft³
  0.5µm Action ≥ 573 particle/ft³
- See Environmental Monitoring S21300.pdf Lot EM21300 shows (batch S21300 "During the Batch Bag Filler Sampling - ISO5" performed on second shift 6/24/2021 resulted in 160.0 particles/ft³ over 0.5µm
  This result exceeds limits of ISO5 classifications, but it was deemed acceptable in accordance with your ~~KR~~ internal specifications and no action was taken.
  S21300 batch was packaged as Lot: BYQ, Released 7/28/2021, Expiration Date: 02/19/2022.

(b) Airborne particulate monitoring of filling operations on the aseptic syringe filling system, Inova SV-122 Automatic Syringe Filling and Sealing Machine with RABS ~~EQ~~ KR Equipment #E0433 does not include all critical locations, the frequency of airborne particulate monitoring is not

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Reg. name SterRx LLC
Trade name
No. and Street 141 Idaho Ave

Details of Inspection adequately supported; and the orientation of particle counter probes is not directed into the flow of air in the monitored location.

(i) Non airborne particulates in close proximity to the plunger vibratory bowl and track. monitoring of

(ii) No scientific justification for the frequency of airborne particulate monitoring performed in the syringe filling system last site pre-batch filling, once per shift during filling, and post filling operations.
See 8-WI-MCB-0012 EM syringe line

(iii) Orientation of the single particle counter probe is not directed into the flow of air in the monitored location near the filler head.

(@) No scientific justification for the frequency of airborne particulate monitoring performed in the critical filling zone of BFS 172, #E0201 at the start, once per shift during filling, and end of filling operations according to
See WI-MCB-0009
Internal specifications do not meet ISO5 classifications
SEE: EM-S21438
QA Product Release S21438
"During the Batch Fill Zone Sampling - ISO 5"
initial performed on 09/09/2021 resulted in 359.0 particles/$ft^3$ over 0.5µm and the end of batch result was 502.0 particles/$ft^3$ over 0.5µm. Exceeds ISO 5 air classifications, but they were deemed acceptable in ~~this~~ its accordance with your internal specifications and there were no actions taken.
Batch S21438 was packaged as Lot: CIS Released 09/29/2021, Expiration Date: 09/04/2022

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Reg. name SterRx LLC
Trade name
No. and Street 141 Idaho Ave

Details of Inspection ~~Obs~~ KES

(14) Refer to Observation 4 of FDA Form 483 - 21 CFR 211.63 Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for cleaning and maintenance.
- BFS 172, #E0201 incorporates machine parts that are particle generating and difficult to sanitize within the ISO7 classified zone of your open parison process equipment.
- Painted machine parts were chipped and missing paint
- Machine frame had signs of surface corrosion.
- Wiring was hanging and secured with tape.
- Tubing was hanging
- Build up of resin residues.
- Tubing and wiring are not routed and secured in a manner to prevent chaffing and particle generation.
The above are all in the critical zone of BFS 172. where parisons are cut and the open parisons are shuttled to the point of aseptic filling.
See 140-FR2 Smoke PR2018-201-SS-Fill Zone Active BFS 172.mp4
140-FR2 Smoke PR2018-201-SS-Shroud Area Activa BFS 172.mp4

(15) Refer to Observation 5 of FDA Form-483- 21 CFR 211.65(6) Substances required for equipment operations such as lubricants and coolants come in contact with components and closures so as to alter the safety, identity, strength, quality or purity of the drug product beyond the official or other established requirements.
On the IV Bag Filling line, #E0432, Bausch Type 529, there has been no evaluation to what extent the solvents

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Inspection # Conducted by
Investigator Kelly Sullivan
Date 9/21/21, 10/12/21, 11/4/21 Time

Reg. name SterRx LLC
Trade name
No. and Street 141 Idaho Ave

Details of Inspection and lubricants contained in sterile silicon spray applied to the vibratory bowl transfer and contaminate IV Bag closures (ports).
"When stoppers are no longer able to feed, more spray can be applied as needed." Step 79 of Compounding - Filling, Batch S210616 S210616.pdf

VES

(16) Refer to Observation 16 of the FDA Form 483, 21 CFR ~~211.192~~ 211.192 Failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.
Lack of complete ~~environmental~~ VES information about the environmental conditions in critical areas during aseptic filling operations necessary for investigation and determination of the full product impact and root cause of environmental excursions and drug product sterility failures. This impedes your ability to determine and implement effective corrective and preventive actions
(1) Since July 2019, there were 3 product sterility failures for lots produced on the IV Bag filling line, #E0432.
(a) see MIR-2019-350.pdf Herbaspirillum huttiense and Burkholderia multivorans Failed to consider whether an inadequate environmental monitoring program for the IV Bag filling line, #E0432 organisms were identified and equipment design deficiencies affecting airflow in critical areas contributed to this event. Batch was rejected.
(b) MIR-2020-008.pdf Organism Burkholderia multivorans was identified. Batch was rejected.
Failed to consider whether an inadequate environmental

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PHARMACY INSPECTION REPORT

Inspection # Conducted by
Investigator Kelly Sullivan
Date 9/21/21, 10/12/21, 11/4/21 Time

Reg. name SterRx LLC
Trade name
No. and Street 141 Idaho Ave

Details of Inspection

monitoring program for the IV Bag filling line, #E0432 and equipment design deficiencies affecting airflow in critical areas contributed to this event.

(c) MIR-2020-127.pdf, Organism Staphylococcus epidermidis grew on one media. Batch was rejected
Failed to consider whether an inadequate environmental monitoring program for the IV Bag filling line, #E0432 and equipment design deficiencies affecting airflow in critical areas contributed to this event.

(2) MIR-2020-099.pdf Organism Bacillus subtilis was identified. Batch was rejected
No assignable cause determined and no CAPA (corrective and preventive actions) initiated. Failed to identify the BFS 172, #E0201 condition and inadequate environmental monitoring program as potentially contributing to this event.

(3) MIR-2021-310, MIR-2021-421 and MIR-2021-463
Batches were released in full.
Did not determine and implement effective preventive actions to control generation of particulate contamination within the ISO 5 classified zone of the IV Bag Filling line, #E0432. Although, your records show drug products produced during periods of high particle count generation were segregated by the Packaging Units, your Quality Unit did not issue a hold status or otherwise control the implicated (segregated) product and require additional consideration for its disposition.

(a) MIR-2021-310.pdf and LWFS Associated With MIR-2021-310.pdf
(i) 6/3/21 - detected 708.0 particles/ft$^3$ over 0.5 µm, exceeding the action limit >573 particles/ft$^3$ over 0.5 µm

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Inspection # Conducted by
Investigator Kelly Sullivan
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Reg. name SterRx LLC
Trade name
No. and Street 141 Idaho ~~St~~ Ave

Details of Inspection on the filling side of the IV Bag filling line, #E0432

(ii) S21272, Lot BXP released: 07/14/2021, Expiration Date: 01/28/2022. 06/15/2021 - detected 119.0 particles/ft³ over 0.5um, exceeding the Action Limit: ≤ 100 particles/ft³ over 0.5um, on the filling side of the IV Bag filling line, #E0432 Batch S21293, Lot: BYJ, released 07/08/2021, Expiration Date: 12/12/2021

(iii) 06/17/2021 - detected 143.0 particles/ft³ over 0.5um, exceeding the Action Limit: ≤ 100 particles/ft³ over 0.5um, ~~exceeding~~ on the filling side of the IV Bag filling line, #E0432 Batch S21287, Lot: BYE, released 07/28/2021, Expiration Date: 02/12/2022. See QA Product release S21287.pdf and Environmental Monitoring S21287.pdf MIR-2021-310 concluded that multiple malfunctions including the stopper arm of Station 1, Station 2 air leak, the conveyor belt and the sampling port pipe in improper position are the root cause of these overaction limit particle counts. Without ample justification, you determined there is no product impact as a result of these over-action-in-process particle count events and each lot was released in full for distribution. See QA Product Release S21287.pdf and Environmental Monitoring S21287.pdf

(b) MIR-2021-~~310.pdf~~ 421.

(i) 07/27/2021, in process environmental monitoring detected 102.0 particles/ft³ over 0.5um ~~of~~ on the filling side of the IV Bag filling line, #E0432 during batch S21349 Determined, without adequate justification, that there is no product impact as a result of this over-action-in-process particle count event and you released the lot in full for distribution. See: QA Product Release S21349.pdf and S21349 Environmental monitoring.pdf Batch S21349, Lot: CAI, released 8/30/2021, expiration: 03/23/2022.

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## PHARMACY INSPECTION REPORT

Inspection # Conducted by
Investigator Kelly Sullivan
Date 9/21/21, 10/12/21 & 11/4/21 Time

Reg. name StuRx LLC
Trade name
No. and Street 141 Idaho Ave

Details of Inspection (ii) 8/02/2021, in-process environmental monitoring detected 108 particles/ft$^3$ over 0.5 um on the filling side of the IV Bag filling line, #E0432 in Batch S21358. Investigation concluded that particles were generated in the filler zone due to a port insertion arm and rails requiring adjustment and loose hardware requiring tightening. You determined, without adequate justification, that there is no product impact as a result of this over-action in-process particle count event and batch S21358, Lot CAR, released on 08/30/2021, Expiration Date: 03/30/2022.

See: QA Product Release S21358.pdf and S21358 Environmental Monitoring.pdf

(iii) 8/4/2021, in-process environmental monitoring detected ~~103.0~~ 162.0 KB particles/ft over 0.5 um on the filling side of the IV Bag Filling line, #E0432 on Batch S21356.
There were no corrective actions reported in your investigation. You determined, without adequate justification, that there is no product impact as a result of this over-action-in-process particle count event and the lot was released in full for distribution.
See: S21356 Environmental Monitoring
QA Product Release S21356

(iv) 8/11/21, in-process environmental monitoring (EM) detected 103.0 particles/ft$^3$ over 0.5 um on the filling side of the IV Bag filling line, #E0432. Investigation concluded that particles were generated in the filler zone due to loose thumb screws and tri-clamps and station 2 stoppering arm was ~~that there~~ KB KB not working properly. The investigation concluded, without adequate justification, that there is no product impact as a result of this over-action-in-process particle count event and disposition of the subject lot is pending review.
See: S21373 Environmental Monitoring

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Reg. name SterRx LLC
Trade name
No. and Street 141 Idaho Ave

Details of Inspection

(c) MIR-2021-463 was for two events of over-action-in-process particle counts on the IV Bag filling line, #E0432 during drug product production as follows:

(i) 8/20/2021, in process environmental monitoring detected 894 ~~148.0~~ particles/ft$^3$ over 0.5um, exceeding the action limit ≤100 particles/ft$^3$ over 0.5um, on the filling side of the IV Bag filling line, #E0432 on batch 521391.

See: 521391 EM.pdf

(ii) 8/23/2021, in process EM detected 148.0 particles/ft$^3$ over 0.5um, exceeding the Action Limit ≤100 particles/ft$^3$ over 0.5um, on the filling side of the IV Bag filling line, #E0432 for batch 521394.

See: 521394 EM.pdf

The investigation MIR-2021-463 determined that equipment malfunction including a leaking solenoid, vacuum generator "blowing out occassionally" and loose hardware are the root cause of these over action limit particle counts. The investigation ~~included~~ concluded, without adequate justification, that there is no product impact as a result of these over-action in-process particle count events and disposition of the subject lots is pending.

(17) & Refer to Observation 7 on the FDA Form 483, 21 CFR 211.67(b)(5) Procedures for the cleaning and maintenance of equipment are deficient regarding the protection of clean equipment from contamination prior to use.

See: MIR-2021-463 SG

Equipment used on the IV Bag filling line #E0432 including drug product component contact change parts and utensils required to be sterile is not adequately protected from contamination prior

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Investigator Kelly Sullivan
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Reg. name SterRx LLC
Trade name
No. and Street 141 Idaho Ave

Details of Inspection to use.

Equipment used on the IV bag filling line #E0432 including drug product component contact change parts and utensils required to be sterile is not adequately protected from contamination before use. Equipment and change parts used in production in the ISO5 classified zone of the IV bag filling line, such as the utensil box, tweezers, scoop, and vibratory bowl is sterilized in Hotpack oven #E0333. This oven is located in an unclassified area adjacent to the process water production area.

PER SOP PRD213 (see 40-SOP-P-0436 (PRD123) - Hotpack oven, "Sterilization of Bag Filler Components and Equipment in Hotpack Oven E0333," the equipment is triple-wrapped in "heavy duty Reynolds aluminum foil or equivalent" prior to sterilization in the oven, and any rips in the outer foil layer may be repaired with high temperature 3M tape. After the wrapped equipment is sterilized, it is removed from the oven and placed on a transfer cart. The cart is moved to the controlled unclassified "transition area," and the outer layer of foil is sprayed with sterile 70% isopropyl alcohol (IPA).

The SOP does not specify how long the equipment may remain in the transition zone wrapped in foil prior to use.

(18) Refer to Observation 8 of the FDA Form 483, 21 CFR 211.113(b) Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.

(1) You have not validated polymer extrusion/sterilization in BFS machine BFS 172, #E0201 and BFS 321-190, #E0581. You have not validated that time temperature conditions of the extrusion (parison formation) process are effective against endotoxin

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Inspection # Conducted by
Investigator Kelly Sullivan
Date 9/21/21, 10/12/21, 11/4/21 Time

Reg. name SterRx LLC
Trade name
No. and Street 141 Idaho Ave

Details of Inspection or spore challenges in the polymeric material that makes up the ~~#~~ US drug product primary container closure.

(2) Operators are permitted to participate in aseptic production on a given line prior to completing a successful aseptic simulation on that line.

re: S. Farrell.pdf 19197 S. Farrell.pdf 19199 S. Farrell.pdf

(a) Operator SF participated in the production of commercial sodium bicarbonate batches S19197 in June 2019 and S19199 in July 2019 on the IV bag filling line #E0432. One of SF's roles is to spray the outer package of the sterile IV bags with sterile Peridox RTU and place the package in the material isolator pass-thru adjacent to the bag filling station, as document in step 83 of batch S19197. The only aseptic simulation documented in SF's training record was on the syringe line #E0433 on 01/27/2021. This occurred both after he participated in commercial aseptic production on the IV bag filler in 2019 and on another production line (syringe line #E0433). No documentation of SF participating in an aseptic simulation on the IV bag filling line #E0432 has been provided. See S19197 S. Farrell

re: F. Lafountain.pdf S19115 F. Lafountain.pdf 19117 F. Lafountain.pdf

(b) Operator FL participated in the production of commercial sodium bicarbonate batches S19115 and S19117 in 03/2019 on the IV bag filling line #E0432. One of FL's roles on this line is collecting prefiltration bioburden samples, as documented in step 18 of batch S19115. He completed an aseptic simulation on this line in 09/2019, after the batches were produced in 03/2019. FL participated in aseptic production prior to participating in an aseptic simulation for that production line.

Recommendation (completed in office)
Investigator
Supervisor

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OPD234
continuation

THE UNIVERSITY OF THE STATE OF NEW YORK
THE STATE EDUCATION DEPARTMENT
OFFICE OF PROFESSIONAL DISCIPLINE

## PHARMACY INSPECTION REPORT

Inspection # Conducted by
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Date 9/21/21, 10/12/21 & 11/4/21 Time

Reg. name SterRx LLC
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Details of Inspection

(19) Refer to Observation 9 of the FDA Form 483, 21 CFR 211.28(a) Protective apparel is not worn as necessary to protect drug products from contamination.
During the inspection on 9/22/2021 I observed packaging and inspection personnel dressed in street clothes and personal footwear handling BFS IV bags containing 150 mEq Sodium Bicarbonate in 5% Dextrose Injection 1,000 ml (12.6 mg/ml) BFS IV Bag, Batch #S21460, in controlled unclassified Packaging Room 148. Personnel were handling the drug product for visual inspection and insertion of the BFS IV bags into secondary packaging (pouches) before sealing.
See: CC-2020-043 SOP for change in Packaging governing requirements.pdf

(20) Yes Refer to Observation 10 of the FDA Form 483, 21 CFR 211.166(a)(3) The written stability program for drug products does not include meaningful test methods.
See SOP-VAL-0099 (0097) Packaging Validation and Evaluation. (193-Stability Program.pdf) It does not evaluate the photostability of light sensitive drug products in the marketed packaging.
Examples are:
① 2mg epinephrine in 0.9% sodium chloride injection 250ml (8mcg/ml)
② 1mg fentanyl in 0.9% sodium chloride injection 100ml (10mcg/ml)
Although in accordance with your protocols the stability samples remain within their marketed secondary packaging consisting of foil-lined pouches throughout the hold time, your firm lacks sufficient evidence through direct testing to show that the secondary packaging adequately protects ~~that~~ drug products from light.

(21) Yes Refer to Observation 11 on the FDA Form 483, 21 CFR 211.25(a)

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## PHARMACY INSPECTION REPORT

Inspection # Conducted by
Investigator Kelly Sullivan
Date 9/21/21, 10/12/21 & 11/4/21 Time

Reg. name SterRx LLC
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Details of Inspection Employees are not given training in the particular operations they perform as part of their function.

(1) See MIR-2020-008 (Close) states that a root cause of the sterility failure for 150 mEq sodium bicarbonate in 5% dextrose batch S19433/Lot ATK, compounded 12/13/19, was a lack of training of an operator (JW) working in the aseptic production of that batch. The batch was produced on IV Bag filling line #E0432, and the organism identified was Burkholderia multivorans. MIR-2019-394 was opened to address JW's production activities prior to training. It shows JW did not complete the prerequisite training module MOD00002, "General GMP" until 12/23/19, 10 days after he participated in batch production. This conflicts with your SOP QAS 209 "Training Program" See QA Product Release S19433 and Manufacturing S19433 Batch Record. See SOP-QA-0163 "Training Program SterRx" It states "Employees, consultants, interns and contractors will be trained on procedures required to perform their job functions prior to performing the tasks described in the procedure."

(2) Operator FL participated in the production of commercial sodium bicarbonate batches S19115 and S19117 on the IV Bag filling line (E0432) in March 2019. FL's training record shows that he was "first trained" to operate the bag filling line in early March 2019 but was not considered "fully trained" until September 6, 2019, which is after batches S19115 and S19117 were produced. Training form TRNOOHH-ASSESS (Version A) defines "first training" as watching the activity and "full training" as performing the activity independently and accurately. FL participated in aseptic production prior to being certified to perform production independently and accurately. SEE S.Farrell.pdf (Column Heads)

Recommendation (completed in office)

Investigator

Supervisor

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PHARMACY INSPECTION REPORT

Inspection # Conducted by
Investigator Kelly Sullivan
Date 9/21/21, 10/12/21 + 11/4/21 Time

Reg. name SterRx LLC
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No. and Street 141 Idaho Ave

Details of Inspection

21 CFR 211.198 (b)(i)

(22) Refer to Observation 12 on the FDA Form 483, ~~21 CFR 211.198(a)~~ (b)
Complaint records are deficient in that they do not include the known reply to the complainant.
See 2019-FDA remediation CustomerComplaints and Adverse Events SOP.pdf (SOP QAS205) does not require a written response to the complainant (SOP-QA-01100)
PC-2019-011 does show an email from the supervising pharmacist to the complainant.
See PC-2019-011.pdf
Email states, "Our sterile phenylephrine IV product is filled and sealed within a sterile ISO5 automated system. The sealed bottle is then labeled and packaged in ~~a clean~~ a clean room.
Actually, this lot was produced on blow-fill-seal (BFS) machine 172 in Filling Room 2. The containers were capped in a separate ISO7 area. The sealed containers were then labeled and packaged (pouched) in an unclassified room.
(2) See PC-2020-135 JEB.pdf
Email from supervising pharmacist to the complainant stating your automated filling system "fills and seals the sterile container within an ISO-5 chamber. this sealed and sterile final product is then inspected, labeled, and placed in the labeled foil pouch in an ISO-7 room."
This lot BCE was produced on the IV bag filling line (E0432) in Filling Room 4 and inspected, labeled, and packaged (pouched) in an unclassified room. The complainant replies to the supervising pharmacist, "This information confirms my understanding of your processes, which was that the package preparation and filling all take place in an ISO5 or better environment and the integrity of the

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## PHARMACY INSPECTION REPORT

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Date 9/21/22, 10/12/21 & 11/4/21. Time

Reg. name SterRx LLC
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Details of Inspection drug was never compromised or in danger of being compromised.'

(23) Must submit Adverse Event Reports to FDA in accordance with the content and format of 21 CFR 310.305 or any successor regulations.

FDA Inspector Ed Mrak said the FDA wants an updated SOP including all the required elements.

~~Office of the Professions~~ DQ
~~Possible~~ These
Potential violations cited in this report ~~will~~ that S management & SP at SterRx have been made aware of, will be reviewed by the Board of Pharmacy and management and the SP of SterRx will be contacted.

End of Report

Recommendation (completed in office)
Investigator
Supervisor

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**FOOD AND DRUG ADMINISTRATION**

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 158-15 Liberty Avenue<br>Jamaica, NY 11433<br>(718) 340-7000 Ext:5301 Fax:(718)662-5661<br>ORAPHARM1_RESPONSES@fda.hhs.gov | 9/21/2021-11/4/2021*<br>FEI NUMBER<br>3010840309 |

| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | |
|---|---|
| Sarah J. McCoy, Director, Plant Operations | |
| **FIRM NAME** | **STREET ADDRESS** |
| SterRx, LLC | 141 Idaho Ave |
| **CITY, STATE, ZIP CODE, COUNTRY** | **TYPE ESTABLISHMENT INSPECTED** |
| Plattsburgh, NY 12903-3987 | Outsourcing Facility 503B |

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:**

## OBSERVATION 1

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically:

1. Blow-Fill-Seal (BFS) operations in your open parison process, including cutting parisons and shuttling of the open parisons to the point of aseptic filling, are conducted under air supplied at lesser quality than ISO 5. Open parisons are exposed during cutting and shuttling within the ISO 7 classified zone to the point of aseptic filling in BFS machines BFS 172, Equipment # E0201 and BFS 321-190, Equipment # E0581.

   Furthermore, you have not evaluated the airflow pattern and airborne particulates in the critical processing zones during operation of BFS machines BFS 172 and BFS 321-190 where parisons are cut and the open parisons are shuttled to the point of aseptic filling.

   BFS 172 is used to produce drug products intended to be sterile including 20mg Phenylephrine HCl in 0.9% Sodium Chloride Injection, Batch: S21159, packaged as Lot: BTQ, Released: 04/30/2021, Expiration Date: 01/30/2022.

   BFS 321-190 is used to produce drug products intended to be sterile including Sodium Bicarbonate 150mEq/1000ml in 5% Dextrose Injection, Batch: S21061, packaged as Lot: BPW, Released: 02/23/2021, Expiration Date: 12/28/2021.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Edmund F Mrak, Investigator<br>Lori M Newman, Investigator | X Edmund F Mrak Investigator Signed By: Edmund F. Mrak Jr -S Date Signed: 11-04-2021 12:58:08 | 11/4/2021 |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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2. The design and construction of the IV Bag filling line, Equipment # E0432, Bausch Type 529 and its enclosure do not provide first pass HEPA-filtered laminar flow air over all critical areas within the ISO 5 classified zone as follows:

   a. Your dynamic airflow pattern study conducted under protocol PR-2018-187-E0432-SS and reported in RPT-2018-187-E0432-SS, Bausch Type 529 Bag Filling and Sealing Machine (E0432) Smoke Study, identified turbulence and upward flow of air near Fill Station #1. This airflow condition was accepted and approved on 10/15/2019 by your firm management without attempting corrective actions.
   b. Direct coverage by first pass HEPA-filtered laminar flow air is not provided over the filling side of the Bausch Type 529 Bag Filling and Sealing Machine where open IV bags are manually removed from wrapping and exposed, held, and passed to the filling section of the line.
   c. First pass HEPA-filtered laminar flow air is blocked by the "plenum" over approximately one half of the vibratory bowl and the track system used to convey sterile closures (ports) to the filling side of the Bausch Type 529 Bag Filling and Sealing Machine. Furthermore, your airflow pattern study reported in RPT-2018-187-E0432-SS, Bausch Type 529 Bag Filling and Sealing Machine (E0432) Smoke Study, did not evaluate the airflow pattern in the area of the vibratory bowl and track system where it is obstructed by the plenum.

   The IV Bag filling line, Equipment # E0432, is used to produce drug products intended to be sterile including Midazolam 1 mg/ml in 0.9% Sodium Chloride, 100ml fill in 100ml IV Bag, Batch: S21066, packaged as Lot: BQB, Released: 05/07/2021, Expiration Date: 11/19/2021.

3. First pass HEPA-filtered laminar flow air is obstructed by the glove port and glove and the vibratory bowl over open, partial bags of syringe plungers held adjacent to the vibratory bowl

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used to hold and convey plungers on the aseptic syringe filling system, Inova SV-122 Automatic Syringe Filling and Sealing Machine with RABS (Restricted Access Barrier Systems), Equipment # E0433. The Inova SV-122 Automatic Syringe Filling and Sealing Machine with RABS (Restricted Access Barrier Systems), Equipment # E0433, is used to produce drug products intended to be sterile including 200 mg Succinylcholine Chloride Injection 10mL (20 mg/mL), Batch: S21476, filled on 09/24/2021.

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**OBSERVATION 2**

Container closure systems do not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.

Specifically:

You do not maintain the sterility of the cap and bag interfacing surfaces and the interstitial space making up the container closure of BFS IV bags containing sterile drug products. Furthermore, the container closure is not designed such that the user can sanitize the surface(s) before spiking for administration to a patient. More specifically:

1. The cap and bag interfacing surfaces and the interstitial space making up the container closure of BFS IV bags containing drug products produced in BFS 172, Equipment # E0201, are not maintained sterile. Filled BFS IV bags produced in BFS 172 are manually offloaded from a conveyor and held in an ISO 7 classified area prior to capping. The capping process includes sanitization of the BFS IV bag tops with non-sterile 3% Hydrogen Peroxide solution, UV light exposure, and drying with filtered air followed by passage under heated air from a "heat gun" that is particle generating by design (due to the brushed blower motor), before capping under ISO 7 conditions. BFS 172 and the offline capping system are used to produce drug products intended to be sterile including 20mg Phenylephrine HCl in 0.9% Sodium Chloride Injection,

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| FIRM NAME<br>SterRx, LLC | STREET ADDRESS<br>141 Idaho Ave |
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Batch: S21159, packaged as Lot: BTQ, Released: 04/30/2021, Expiration Date: 01/30/2022.

2. The cap and bag interfacing surfaces and the interstitial space making up the container closure of BFS IV bags containing drug products produced in BFS 321-190, Equipment # E0581, are not maintained sterile and are exposed to less than ISO 5 environmental conditions. BFS IV bags containing drug products produced in BFS 321-190 are conveyed and capped in-line under ISO 7 classified conditions. BFS 321-190, Equipment # E0581, is used to produce drug products intended to be sterile including Sodium Bicarbonate 150mEq/1000ml in 5% Dextrose Injection, Batch: S21061, packaged as Lot: BPW, Released: 02/23/2021, Expiration Date: 12/28/2021.

**OBSERVATION 3**

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically:

1. Your surface and airborne viable monitoring program for aseptic filling operations is not designed and conducted to provide meaningful data to support the quality of your drug products intended to be sterile. Your firm's procedures permit surface and air samples from within ISO 5 environments to yield microbiological contaminants of 1 CFU (colony forming unit) without conducting an investigation. More specifically:

    a. Prior to revision in August 2021 your environmental monitoring plans and specifications for surface viable monitoring permitted 1 CFU microbial recoveries on filling needles and mandrels (BFS) in the critical filling zones of the IV Bag filling line, Equipment # E0432; Syringe Line, Equipment # E0433; BFS 172, Equipment # E0201; and BFS 321-190, Equipment # E0581 without requirements for investigation and action. For example:

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**FOOD AND DRUG ADMINISTRATION**

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| CITY, STATE, ZIP CODE, COUNTRY<br>Plattsburgh, NY 12903-3987 | TYPE ESTABLISHMENT INSPECTED<br>Outsourcing Facility 503B |

i. Your environmental monitoring plan, Environmental Monitoring – Bag Filler E0432, permitted 1 CFU microbial recoveries on filling needles in the critical filling zone of the IV Bag filling line, Equipment # E0432. Your environmental monitoring record for filling Midazolam 1 mg/ml in 0.9% Sodium Chloride, 100ml fill in 100ml IV Bag, Batch: S21066, Environmental Monitoring Lot: EM21066 on the IV Bag filling line, Equipment # E0432 shows that "Post Batch Bag Filler Sampling – ISO 5" performed on 03/24/2021 recovered 1 CFU from the surface of the right filling needle. You did not investigate or take any other action, and the batch was packaged as Lot: BQB, Released: 05/07/2021, Expiration Date: 11/19/2021.

ii. Your environmental monitoring plan, Environmental Monitoring – Syringe Line, permitted 1 CFU microbial recoveries on filling needles in the critical filling zone of the Syringe Line, Equipment # E0433. Your environmental monitoring record for filling Succinylcholine 20mg/ml in 0.4% Sodium Chloride – 10ml Pre-Filled Syringe, Batch: S20141, Environmental Monitoring Lot: EM20141 on the Syringe Line, Equipment # E0433 shows that "Post Batch Syringe Line Sampling – ISO 5" performed on 04/06/2020 recovered 1 CFU from the surface of the North filling needle. You did not investigate or take any other action, and the batch was packaged as Lot: AZX, Released: 05/20/2020, Expiration Date: 07/05/2020.

iii. Your environmental monitoring plans, Environmental Monitoring – ISO 7 Deflasher/Capper and ISO 8 Fill Room (FR6) and Environmental Monitoring – ISO 8 Cleanroom, permitted 1 CFU microbial recoveries on filling mandrels in the critical filling zone of the BFS 321-190, Equipment # E0581. Your environmental monitoring record for filling Sodium Bicarbonate 150mEq/1000ml

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in 5% Dextrose Injection, Batch: S21185, Environmental Monitoring Lot: EM21185 on the BFS 321-190, Equipment # E0581 shows that "Post Batch BFS 321 Fill Zone Sampling – ISO 5" performed on 04/27/2021 recovered 1 CFU from the surface of the 3rd Mandrel From the Front – Left Side. You did not investigate or take any other action, and the batch was packaged as Lot: BUP, Released: 05/21/2021, Expiration Date: 03/23/2022.

Additionally, your environmental monitoring record for filling Sodium Bicarbonate 150mEq/1000ml in 5% Dextrose Injection, Batch: S21010, Environmental Monitoring Lot: EM21010 on the BFS 321-190, Equipment # E0581 shows that "Post Batch BFS 321 Fill Zone Sampling – ISO 5" performed on 01/13/2021 recovered 1 CFU from the surface of the 3rd (middle) Mandrel – Right Side. You did not investigate or take any other action, and the batch was packaged as Lot: BNX, Released: 02/17/2021, Expiration Date: 12/09/2021.

iv. Your environmental monitoring plan, Environmental Monitoring – ISO 7 Cleanroom *with Sanitization Tunnel and Capper*, permitted 1 CFU microbial recoveries on filling mandrels in the critical filling zone of the BFS 172, Equipment # E0201. Your environmental monitoring record for filling Norepinephrine 8mg in 0.9% Sodium Chloride Injection-250ml, Batch: S20022, Environmental Monitoring Lot: EM20022 on the BFS 172, Equipment # E0201 shows that "Post Batch Fill Zone Sampling – ISO 5" performed on 01/16/2020 recovered 1 CFU from the surface of the 3rd (middle) Mandrel – Left Side. You did not investigate or take any other action, and the batch was packaged as Lot: AVA, Released: 04/09/2020, Expiration Date: 08/22/2020.

b. Your current environmental monitoring plans and specifications for airborne and surface viable monitoring permit 1 CFU recoveries within the ISO 5 classified zones inside the enclosures of the IV Bag filling line, Equipment # E0432 and Syringe Line, Equipment #

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**FOOD AND DRUG ADMINISTRATION**

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E0433 without requirements for investigation and action. For example:

i. Your Work Instruction WI-MCB-0017 for drug products filled on the IV Bag filling line, Equipment # E0432 permits surface and air samples from within ISO 5 environment to yield microbiological contaminants of 1 CFU without investigation and action. For example:

1. Your environmental monitoring record for filling Midazolam 1mg/ml in 0.9% Sodium Chloride, 50ml fill in 100ml IV Bag, Batch: S21160, Environmental Monitoring Lot: EM21160 on the IV Bag filling line, Equipment # E0432 shows that "Post Batch Bag Filler Sampling – ISO 5" performed on 04/07/2021 recovered 1 CFU from the surface of the Bag Filler Interior, Filling Side Interior Plexiglass Left. You did not investigate or take any other action, and the batch was packaged as Lot: BTR, Released: 05/07/2021, Expiration Date:12/02/2021.

2. Your environmental monitoring record for filling 150 mEq Sodium Bicarbonate in 5% Dextrose Injection, 1000ml, Batch: S20171, Environmental Monitoring Lot: EM20171 on the IV Bag filling line, Equipment # E0432 shows that airborne viable monitoring "During the Batch Bag Filler Sampling – ISO 5" performed on 04/23/2020 recovered 1 CFU from the Bag Filler Side. You did not investigate or take any other action, and the batch was packaged as Lot: BBB, Released: 05/13/2020, Expiration Date: 03/18/2021.

ii. Your Work Instruction WI-MCB-0012 for drug products filled on the Syringe Line, Equipment # E0433 permits surface and air samples from within the ISO 5 environment to yield microbiological contaminants of 1 CFU without investigation

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| FIRM NAME<br>SterRx, LLC | STREET ADDRESS<br>141 Idaho Ave |
| CITY, STATE, ZIP CODE, COUNTRY<br>Plattsburgh, NY 12903-3987 | TYPE ESTABLISHMENT INSPECTED<br>Outsourcing Facility 503B |

and action.

c. Your current environmental monitoring plans and specifications for airborne viable monitoring permit 1 CFU recoveries in the critical filling zones of BFS 172, Equipment # E0201; and BFS 321-190, Equipment # E0581 without requirements for investigation and action. For example:

i. Your Work Instruction WI-MCB-0009 for drug products filled on BFS 172, Equipment # E0201 permits air samples from within the ISO 5 Fill Zone to yield microbiological contaminants of 1 CFU without investigation and action. For example:

1. Your environmental monitoring record for filling 20mg Phenylephrine HCl in 0.9% Sodium Chloride Injection, Batch: S21159, Environmental Monitoring Lot: EM21159 on the BFS 172, Equipment # E0201 shows that airborne viable monitoring "During the Batch Fill Zone Sampling – ISO 5" performed on 04/05/2021 recovered 1 CFU from the Fill Zone (STA). You did not investigate or take any other action, and the batch was packaged as Lot: BTQ, Released: 04/30/2021, Expiration Date: 01/30/2022

ii. Your Work Instruction WI-MCB-0011 for drug products filled on BFS 321-190, Equipment # E0581 permits air samples from within the ISO 5 Fill Zone to yield microbiological contaminants of 1 CFU without investigation and action. For example:

1. Your environmental monitoring record for filling Sodium Bicarbonate 150mEq/1000ml in 5% Dextrose Injection, Batch: S21061, Environmental

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**FOOD AND DRUG ADMINISTRATION**

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Monitoring Lot: EM21061 on the BFS 321-190, Equipment # E0581 shows that airborne viable monitoring "Post Batch BFS 321 Fill Zone Sampling – ISO 5" performed on 02/01/2021 recovered 1 CFU from the from the Fill Zone (STA). You did not investigate or take any other action, and the batch was packaged as Lot: BPW, Released: 02/23/2021, Expiration Date: 12/28/2021.

2. Your airborne particulate monitoring program for aseptic filling operations is not designed and conducted to provide meaningful data to support the quality of your drug products intended to be sterile. You do not monitor airborne particulates to ISO 5 air classifications in all critical locations; the frequency of airborne particulate monitoring is not adequately supported; and the orientation of particle counter probes is not directed into the flow of air in monitored locations. For example:

   a. Airborne particulate monitoring of filling operations on the IV Bag filling line, Equipment # E0432, Bausch Type 529, does not include all critical locations; the frequency of airborne particulate monitoring is not adequately supported; and the orientation of particle counter probes is not directed into the flow of air in monitored locations. More specifically:

      i. You do not monitor airborne particulates in close proximity to open IV bags that are manually unwrapped and held for filling.
      ii. You do not provide scientific justification for the frequency of airborne particulate monitoring performed in the filler side and the injection port feed side pre-batch filling, once per shift during filling, and post filling operations according to your Work Instruction WI-MCB-0017.
      iii. The orientation of particle counter probes is not directed into the flow of air in monitored locations near the filler and the port bowl and track.

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Furthermore, your specifications written in Work Instruction WI-MCB-0017 and batch monitoring records for airborne particle counts taken on the filler side of the IV Bag filling line during filling of 150mEq Sodium Bicarbonate in 5% Dextrose Injection and 125mg Diltiazem D5W / 125mg Diltiazem 0.7% Sodium Chloride Injection do not meet clean area air classifications for ISO 5 as follows:

- 150mEq Sodium Bicarbonate in 5% Dextrose Injection:
  - 0.5µm Alert ≥460 particles/ft$^3$
  - 0.5µm Action: ≥485 particle/ft$^3$

- 125mg Diltiazem D5W / 125mg Diltiazem 0.7% Sodium Chloride Injection:
  - 0.5µm Alert ≥ 546 particle/ft$^3$
  - 0.5µm Action > 573 particle/ft$^3$

You do not investigate excursions over ISO 5 air classifications that are within your internal specifications shown above. For example: Your environmental monitoring record for filling 125 mg Diltiazem D5W/125mg Diltiazem 0.7% Sodium Chloride, Batch: S21300, Environmental Monitoring Lot: EM21300 on the IV Bag filling line, Equipment # E0432, Bausch Type 529 shows that "During the Batch Bag Filler Sampling – ISO 5" performed on second shift 06/24/2021 resulted in 160.0 particles/ft$^3$ over 0.5 µm. This result exceeds limits established in ISO 5 air classifications, but it was deemed acceptable in accordance with your internal specifications and there were no actions taken. The batch was packaged as Lot: BYQ, Released: 07/28/2021, Expiration Date: 02/19/2022.

b. Airborne particulate monitoring of filling operations on the aseptic syringe filling system,

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Inova SV-122 Automatic Syringe Filling and Sealing Machine with RABS (Restricted Access Barrier Systems) Equipment # E0433 does not include all critical locations; the frequency of airborne particulate monitoring is not adequately supported; and the orientation of particle counter probes is not directed into the flow of air in the monitored location. More specifically:

i. You do not monitor airborne particulates in close proximity to the plunger vibratory bowl and track.

ii. You do not provide scientific justification for the frequency of airborne particulate monitoring performed in the syringe filling system east side pre-batch filling, once per shift during filling, and post filling operations according to your Work Instruction WI-MCB-0012.

iii. The orientation of the single particle counter probe is not directed into the flow of air in the monitored location near the filler head.

The Inova SV-122 Automatic Syringe Filling and Sealing Machine with RABS (Restricted Access Barrier Systems), Equipment # E0433, is used to produce drug products intended to be sterile including 200 mg Succinylcholine Chloride Injection 10mL (20 mg/mL), Batch: S21476 filled on 09/24/2021.

c. You do not provide scientific justification for the frequency of airborne particulate monitoring performed in the critical filling zone of BFS 172, Equipment # E0201 at the start, once per shift during filling, and end of filling operations according to your Work Instruction WI-MCB-0009 and batch monitoring records.

Furthermore, your specifications written in Work Instruction WI-MCB-0009 and batch monitoring records for airborne particle count of 0.5µm Alert > 7058 particles/ft³, Action >

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7723 particles/ ft³, in the critical filling zone of BFS 172, Equipment # E0201, do not meet clean area air classifications for ISO 5. No corrective actions are taken for excursions over ISO 5 air classifications that are within your internal specifications. For example: Your environmental monitoring record for filling 4 mg Norepinephrine in 0.9% Sodium Chloride Injection 250 mL (16 mcg/ml) BFS IV Bag, Batch: S21438, Environmental Monitoring Lot: EM21438 in BFS 172 shows that "During the Batch Fill Zone Sampling – ISO 5" initial performed on 09/09/2021 resulted in 359.0 particles/ft³ over 0.5 µm and the end of batch result was 502.0 particles/ft³ over 0.5 µm. These results exceed the limits established in Class 100 / ISO 5 air classifications, but they were deemed acceptable in accordance with your internal specifications and there were no actions taken. The batch was packaged as Lot: CDS, Released: 09/29/2021, Expiration Date: 09/04/2022.

**OBSERVATION 4**

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its cleaning and maintenance.

Specifically:

The design and construction of BFS 172, Equipment # E0201, incorporates machine parts that are particle generating and difficult to sanitize within the ISO 7 classified zone of your open parison process equipment. During the inspection we observed the following within the ISO 7 Classified shrouded area of BFS 172: painted machine parts were chipped and missing paint; the machine frame had signs of surface corrosion; wiring was hanging and secured with tape; tubing was hanging; and there was a build-up of resin residues. Additionally, tubing and wiring are not routed and secured in a manner to prevent chaffing and particle generation. The ISO 7 classified area where these conditions were observed houses the critical processing zone of BFS 172, where parisons are cut and the open parisons are shuttled to the point of aseptic filling. BFS 172 is used to produce drug products intended to be sterile including 20mg

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Phenylephrine HCl in 0.9% Sodium Chloride Injection, Batch: S21159, packaged as Lot: BTQ, Released: 04/30/2021, Expiration Date: 01/30/2022.

**OBSERVATION 5**

Substances required for equipment operations such as lubricants and coolants come in contact with components and closures so as to alter the safety, identity, strength, quality or purity of the drug product beyond the official or other established requirements.

Specifically:

On the IV Bag filling line, Equipment # E0432, Bausch Type 529, you have not evaluated whether or to what extent solvents and lubricants contained in sterile silicon spray applied to the vibratory bowl transfer to and contaminate IV Bag closures (ports). In accordance with your manufacturing batch records, during setup and operation of IV Bag filling line, Equipment # E0432, Bausch Type 529, you apply sterile silicon spray onto the stainless-steel vibratory bowl to facilitate movement of sterile closures (ports) to the filling side of the machine. Your manufacturing batch records indicate that the machine may be stopped during the filling operation and "When stoppers are no longer able to feed, more spray can be applied as needed". The IV Bag filling line, Equipment # E0432, is used to produce drug products intended to be sterile including Midazolam 1 mg/ml in 0.9% Sodium Chloride, 100ml fill in 100ml IV Bag, Batch: S21066, packaged as Lot: BQB, Released: 05/07/2021, Expiration Date: 11/19/2021.

**OBSERVATION 6**

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There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically:

You lack complete information about the environmental conditions in critical areas during aseptic filling operations necessary for investigation and determination of the full product impact and root cause of environmental excursions and drug product sterility failures. Furthermore, your lack of complete environmental data and root cause identification diminishes your ability to determine and implement effective corrective and preventive actions. For example:

1. Since June 2019 you have reported three drug product sterility failures for lots produced on the IV Bag filling line, Equipment # E0432. Conclusions from your investigations are as follows:
   a. Your investigation, MIR-2019-350, for 150mEq Sodium Bicarbonate in 5% Dextrose batch S19378, Lot ARB, manufactured on 10/24/2019, out of specification (OOS) results for Particulate Matter per USP<788> and Not Sterile per USP<71>, was inconclusive. Organisms recovered were identified as *Herbaspirillum huttiense* and *Burkholderia multivorans*. The batch was rejected. There was no assignable cause determined and no CAPA initiated. Your investigation failed to attempt identification of the particulate matter in the drug product samples and use such information to assist in determining the root cause of the event and effective CAPA. Your investigation failed to consider whether an inadequate environmental monitoring program for the IV Bag filling line, Equipment # E0432 and equipment design deficiencies affecting airflow in critical areas contributed to this event.

   b. Your investigation, MIR-2020-008, for 150mEq Sodium Bicarbonate in 5% Dextrose batch S19433, Lot ATK, manufactured on 12/13-14/2019, OOS result Not Sterile per USP<71>, identified inadequate methods for cleaning and sanitization of the IV Bag filling line following maintenance interventions. The organism recovered was identified as

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*Burkholderia multivorans*. The batch was rejected. Your investigation failed to consider whether an inadequate environmental monitoring program for the IV Bag filling line, Equipment # E0432 and equipment design deficiencies affecting airflow in critical areas contributed to this event.

c. Your investigation, MIR-2020-127, for 150mEq Sodium Bicarbonate in 5% Dextrose batch S20107, Lot AYP, manufactured on 03/18-19/2020, OOS result Not Sterile per USP<71>, was inconclusive. The batch was rejected. Although there was no assignable cause attributable to the contract laboratory your investigation concluded that the most likely cause of this event was contamination during testing since the analyst performed 51 tests on the day that the subject sample was tested, and the organism (*Staphylococcus epidermidis*) only grew in one media. Your investigation failed to consider whether an inadequate environmental monitoring program for the IV Bag filling line, Equipment # E0432 and equipment design deficiencies affecting airflow in critical areas contributed to this event.

2. Your investigation, MIR-2020-099, for 150mEq Sodium Bicarbonate in 5% Dextrose batch S20107, Lot AYP, manufactured on BFS 172, Equipment # E0201, on 03/18-19/2020, OOS result Not Sterile per USP<71>, was inconclusive. The organism recovered was identified as *Bacillus subtilis*. The batch was rejected. There was no assignable cause determined and no CAPA initiated. Your investigation failed to identify the BFS 172, Equipment # E0201 condition and inadequate environmental monitoring program as potentially contributing to this event.

3. Your investigations including MIR-2021-310, MIR-2021-421, and MIR-2021-463 in response to airborne particle count exceeding action limits in the critical zone of the IV Bag filling line, Equipment # E0432 conclude that multiple equipment related issues inherent to the filling process on the IV Bag filling line are the root cause of the subject events. You determined that there was no product impact resulting from these events due to acceptable viable monitoring results, visual inspection results, and finished product release testing results and all batches/lots implicated in these

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investigations were released in full. You did not determine and implement effective preventive actions to control generation of particulate contamination within the ISO 5 classified zone of the IV Bag filling line, Equipment # E0432. Furthermore, although your records indicate that drug products produced during periods of high particle count generation were segregated by the Packaging Unit, your Quality Unit did not issue a hold status or otherwise control the implicated (segregated) product and require additional consideration for its disposition.

For example:

a. Your investigation, MIR-2021-310, was written for three events of over-action in-process particle counts on the IV Bag filling line, Equipment # E0432 during production of drug products as follows:

   i. On 06/03/2021, in-process environmental monitoring detected 708.0 particles/ft³ over 0.5 µm, exceeding the Action Limit: >573 particles/ft³ over 0.5 µm, on the filling side of the IV Bag filling line, Equipment # E0432, while filling 125 mg Diltiazem D5W/125mg Diltiazem 0.7% Sodium Chloride Batch: S21272, Lot: BXP, Released: 07/14/2021, Expiration Date: 01/28/2022.

   ii. On 06/15/2021, in-process environmental monitoring detected 119.0 particles/ft³ over 0.5 µm, exceeding the Action Limit: ≤100 particles/ft³ over 0.5 µm, on the filling side of the IV Bag filling line, Equipment # E0432, while filling 100 mg Morphine Sulfate 1 mg/ml in 5% Dextrose 100 ml, Batch: S21293, Lot: BYJ, Released: 07/08/2021, Expiration Date: 12/12/2021.

   iii. On 06/17/2021, in-process environmental monitoring detected 143.0 particles/ft³ over 0.5 µm, exceeding the Action Limit: ≤100 particles/ft³ over 0.5 µm, on the filling side of the IV Bag filling line, Equipment # E0432, while filling 1 mg/ml Midazolam in 0.9% Sodium Chloride 100 ml, Batch: S21287, Lot: BYE, Released: 07/28/2021, Expiration Date: 02/12/2022.

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Your investigation, MIR-2021-310, concluded that multiple equipment malfunctions including the stopper arm of Station 1, Station two air leak, the conveyor belt and the sampling port pipe in improper position are the root cause of these overaction limit particle counts. You determined, without adequate justification, that there is no product impact as a result of these over-action in-process particle count events and you released each lot in full for distribution.

b. Your investigation, MIR-2021-421, was written for four events of over-action in-process particle counts (Action Limit: ≤100 particles/ft³ over 0.5 µm) on the IV Bag filling line, Equipment # E0432 during production of drug products as follows:

i. On 07/27/2021, in-process environmental monitoring detected 102.0 particles/ft³ over 0.5 µm on the filling side of the IV Bag filling line, Equipment # E0432, while filling 1 mg Fentanyl in 0.9% Sodium Chloride Injection 100 ml (10 mcg/ml) Batch: S21349, Lot: CAI, Released: 08/30/2021, Expiration Date: 03/23/2022. Your investigation concluded that the port vibratory bowl was activated during sampling and produced particles detected on the filling side of the machine. This implies that the filling system and designed flow of HEPA filtered air is incapable of excluding particles generated on the component side from the filling side near the filling needles. You determined, without adequate justification, that there is no product impact as a result of this over-action in-process particle count event and you released the lot in full for distribution.

ii. On 08/02/2021, in-process environmental monitoring detected 108.0 particles/ft³ over 0.5 µm on the filling side of the IV Bag filling line, Equipment # E0432, while filling 2.5 mg Fentanyl in 0.9% Sodium Chloride Injection 250 ml (10 mcg/ml) Batch: S21358, Lot: CAR, Released: 08/30/2021, Expiration Date: 03/30/2022. Your investigation concluded that particles were generated in the filler zone due to a port insertion arm and rails requiring adjustment and loose hardware requiring tightening. You determined, without adequate justification, that there is no product impact as a

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result of this over-action in-process particle count event and you released the lot in full for distribution.

iii. On 08/04/2021, in-process environmental monitoring detected 162.0 particles/ft³ over 0.5 µm on the filling side of the IV Bag filling line, Equipment # E0432, while filling 1 mg Fentanyl in 0.9% Sodium Chloride Injection 100 ml (10 mcg/ml) Batch: S21356, Lot: CAP, Released: 09/08/2021, Expiration Date: 04/01/2022. There were no corrective actions reported in your investigation. You determined, without adequate justification, that there is no product impact as a result of this over-action in-process particle count event and you released the lot in full for distribution.

iv. On 08/11/2021, in-process environmental monitoring detected 103.0 particles/ft³ over 0.5 µm on the filling side of the IV Bag filling line, Equipment # E0432, while filling 1 mg Fentanyl in 0.9% Sodium Chloride Injection 100 ml (10 mcg/ml) Batch: S21373, Lot: CBG. Your investigation concluded that particles were generated in the filler zone due to loose thumb screws and tri-clamps and station 2 stoppering arm was not working properly. Your investigation concluded, without adequate justification, that there is no product impact as a result of this over-action in-process particle count event and disposition of the subject lot is pending review.

c. Your investigation, MIR-2021-463, was written for two events of over-action in-process particle counts on the IV Bag filling line, Equipment # E0432 during production of drug products as follows:

i. On 08/20/2021, in-process environmental monitoring detected 894.0 particles/ft³ over 0.5 µm, exceeding the Action Limit: ≤100 particles/ft³ over 0.5 µm, on the filling side of the IV Bag filling line, Equipment # E0432, while filling 1 mg/ml Midazolam in 0.9% Sodium Chloride 100 ml, Batch: S21391, Lot: CBY.

ii. On 08/23/2021, in-process environmental monitoring detected 148.0 particles/ft³ over 0.5 µm, exceeding the Action Limit: ≤100 particles/ft³ over 0.5 µm, on the filling side of the IV Bag filling line, Equipment # E0432, while filling 1 mg/ml

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FOOD AND DRUG ADMINISTRATION

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| | FEI NUMBER<br>3010840309 |

| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | |
|---|---|
| Sarah J. McCoy, Director, Plant Operations | |
| FIRM NAME<br>SterRx, LLC | STREET ADDRESS<br>141 Idaho Ave |
| CITY, STATE, ZIP CODE, COUNTRY<br>Plattsburgh, NY 12903-3987 | TYPE ESTABLISHMENT INSPECTED<br>Outsourcing Facility 503B |

Midazolam in 0.9% Sodium Chloride 100 ml, Batch: S21394, Lot: CCB.

Your investigation, MIR-2021-463, determined that equipment malfunctions including a leaking solenoid, vacuum generator "blowing out occasionally" and loose hardware are the root cause of these overaction limit particle counts. Your investigation concluded, without adequate justification, that there is no product impact as a result of these over-action in-process particle count events and disposition of the subject lots is pending review.

**OBSERVATION 7**

Procedures for the cleaning and maintenance of equipment are deficient regarding the protection of clean equipment from contamination prior to use.

Specifically:

Equipment used on the IV bag filling line #E0432 including drug product component contact change parts and utensils required to be sterile is not adequately protected from contamination before use. Equipment and change parts used in production in the ISO 5 classified zone of the IV bag filling line, such as the utensil box, tweezers, scoop, and vibratory bowl is sterilized in Hotpack oven #E0333. This oven is situated in an unclassified area adjacent to the process water production area. Per SOP PRD213, "Sterilization of Bag Filler Components and Equipment in Hotpack Oven E0333," the equipment is triple-wrapped in "heavy duty Reynolds aluminum foil or equivalent" prior to sterilization in the oven, and any rips in the outer foil layer may be repaired with high temperature 3M tape. After the wrapped equipment is sterilized, it is removed from the oven and placed on a transfer cart, the cart is moved to the controlled unclassified "transition area," and the outer layer of foil is sprayed with sterile 70% IPA.

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The SOP does not specify for how long the equipment may remain in the transition zone wrapped in foil prior to use.

**OBSERVATION 8**

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.

Specifically:

1. You have not validated polymer extrusion/sterilization in BFS machines BFS 172, Equipment # E0201 and BFS 321-190, Equipment # E0581. More specifically you have not validated that time temperature conditions of the extrusion (parison formation) process are effective against endotoxin or spore challenges in the polymeric material that makes up the drug product primary container closure.

   BFS 172 is used to produce drug products intended to be sterile including 20mg Phenylephrine HCl in 0.9% Sodium Chloride Injection, Batch: S21159, packaged as Lot: BTQ, Released: 04/30/2021, Expiration Date: 01/30/2022.

   BFS 321-190 is used to produce drug products intended to be sterile including Sodium Bicarbonate 150mEq/1000ml in 5% Dextrose Injection, Batch: S21061, packaged as Lot: BPW, Released: 02/23/2021, Expiration Date: 12/28/2021.

2. Operators are permitted to participate in aseptic production on a given line prior to completing a successful aseptic simulation on that line. For example:

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a. Operator SF participated in the production of commercial sodium bicarbonate batches S19197 in June 2019 and S19199 in July 2019 on the IV bag filling line # E0432. One of his roles is to spray the outer package of the sterile IV bags with sterile Peridox RTU and place the package in the material isolator pass-thru adjacent to the bag filling station, as documented in step 83 of batch S19197. The only aseptic simulation documented in SF's training record was on the syringe line # E0433 on January 27, 2021. This occurred both after he participated in commercial aseptic production on the IV bag filler in 2019 and on a different production line (syringe line # E0433). No documentation of SF participating in an aseptic simulation on the IV bag filling line # E0432 has been provided.

b. Operator FL participated in the production of commercial sodium bicarbonate batches S19115 and S19117 in March 2019 on the IV bag filling line # E0432. One of his roles on this line is collecting prefiltration bioburden samples, as documented in step 18 of batch s19115. He completed an aseptic simulation on this line in September 2019, after the batches were produced in March 2019. Thus, FL participated in aseptic production prior to participating in an aseptic simulation for that production line.

**OBSERVATION 9**

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically:

You permit personnel to enter packaging areas and conduct packaging operations in their street clothes and footwear. Your Change Control, CC No. CC-2020-043, approved on 04/09/2020, permitted temporary deviation from your procedure ADM102, Facility and Gowning, due to a shortage of supplies. During the inspection on 09/22/2021 we observed packaging and inspection personnel dressed

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in street clothes and personal footwear handling BFS IV bags containing 150 mEq Sodium Bicarbonate in 5% Dextrose Injection 1,000 mL (12.6mg/mL) BFS IV Bag, Batch # S21460, in controlled unclassified Packaging Room 148. Personnel in street clothes, handled the drug product for visual inspection and insertion of the BFS IV bags into secondary packaging (pouches) before sealing.

**OBSERVATION 10**

The written stability program for drug products does not include meaningful test methods.

Specifically:

Your stability program SOP-VAL-0097 does not evaluate the photostability of light-sensitive drug products in the marketed packaging. Examples of such products are 2 mg epinephrine in 0.9% sodium chloride injection 250 mL (8 mcg/mL) and 1 mg fentanyl in 0.9% sodium chloride injection 100 mL (10 mcg/mL). Although in accordance with your protocols the stability samples remain within their marketed secondary packaging consisting of foil-lined pouches throughout the hold time, your firm lacks sufficient evidence through direct testing to show that the secondary packaging adequately protects drug products from light.

**OBSERVATION 11**

Employees are not given training in the particular operations they perform as part of their function.

Specifically:

1. Investigation MIR-2020-008 states that a root cause of the sterility failure for 150 mEq sodium bicarbonate in 5% dextrose batch S19433/Lot ATK, manufactured 12/13/19, was a lack of

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| Sarah J. McCoy, Director, Plant Operations | |
| FIRM NAME | STREET ADDRESS |
| SterRx, LLC | 141 Idaho Ave |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Plattsburgh, NY 12903-3987 | Outsourcing Facility 503B |

training of an operator (JW) participating in the aseptic production of that batch. The batch was produced on IV Bag filling line #E0432, and the organism was identified as *Burkholderia multivorans*. MIR-2019-394 was opened to address JW's production activities prior to training. It indicates that he did not complete the prerequisite training module MOD00002 "General GMP" until 12/23/19, 10 days after he participated in batch production. This practice conflicts with your SOP QAS 209 "Training Program," which states, "Employees, consultants, interns and contractors will be trained on procedures required to perform their job functions prior to performing the tasks described in the procedure.".

2. Operator FL participated in the production of commercial sodium bicarbonate batches S19115 and S19117 on the IV bag filling line (E0432) in March 2019. His training record shows that he was "first trained" to operate the bag filling line in early March 2019 but was not considered "fully trained" until September 6, 2019, which is after batches S19115 and S19117 were produced. Training form TRN00114-ASSESS (Version A) defines "first training" as watching the activity, and "full training" as performing the activity independently and accurately. Thus, FL participated in aseptic production prior to being certified to perform production independently and accurately.

**OBSERVATION 12**

Complaint records are deficient in that they do not include the known reply to complainant.

Specifically:

Complainants do not always receive a final written response to their drug product complaint. For instance, you have received complaints for four adverse events since the last inspection and investigated these, but your records do not include a final written response to the complainant regarding investigation findings. Firm management confirmed that a written response was not issued. SOP QAS205 "Customer Complaints and Adverse Events" also does not require a written response to the complainant.

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Some complaint records do include e-mail correspondence between SterRx personnel and complainants, but without a formal final response. For example:

1. Product complaint PC-2019-011, concerning a hair found on the outside of a pouch of 20 mg phenylephrine in 0.9% sodium chloride (lot AMI, manufactured 29 March 2019), contains the following text in an e-mail from the supervising pharmacist to the complainant: "Our sterile phenylephrine IV product is filled and sealed within a sterile ISO5 automated system. The sealed bottle is then labeled and packaged in a clean room."
   This lot was produced on blow-fill-seal (BFS) machine 172 (E0201) in Filling Room 2. The containers were capped in a separate ISO 7 area. The sealed containers were then labeled and packaged (pouched) in an unclassified room.

2. Complaint record PC-2020-135, regarding broken IV bags of 150 mEq sodium bicarbonate in 5% dextrose (Lot BCE, manufactured 13 May 2020) includes an e-mail from the supervising pharmacist to the complainant stating that your automated filling system "fills and seals the sterile container within an ISO5 chamber. This sealed and sterile final product is then inspected, labeled, and placed in the labeled foil pouch in an ISO7 room." This lot was produced on the IV bag filling line(E0432) in Filling Room 4 and inspected, labeled, and packaged (pouched) in an unclassified room. The complainant replies to the supervising pharmacist, "This information confirms my understanding of your processes, which was that the package preparation and filling all take place in an ISO5 or better environment and the integrity of the drug was never compromised or in danger of being compromised."

***DATES OF INSPECTION**

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9/21/2021(Tue), 9/22/2021(Wed), 9/23/2021(Thu), 9/24/2021(Fri), 9/27/2021(Mon), 9/28/2021(Tue), 9/29/2021(Wed), 9/30/2021(Thu), 10/01/2021(Fri), 10/12/2021(Tue), 10/19/2021(Tue), 10/27/2021(Wed), 11/04/2021(Thu)

Lori M Newman
Investigator
Signed By: 2003217755
Date Signed: 11-04-2021 12:58:56
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FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OFFICE OF PHARMACEUTICAL QUALITY OPERATIONS

U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
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Telephone: (973) 331-4900
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www.fda.gov

**CERTIFIED MAIL**
**RETURN RECEIPT REQUESTED**

**WARNING LETTER**
**WL # 636636**

July 18, 2022

Dr. Peter A. Kaemmerer
Chief Executive Officer
Sagent Pharmaceuticals, Inc.
1901 N. Roselle Road, Suite 450
Schaumburg, IL 60195

Dear Dr. Kaemmerer:

You registered your facility with the U.S. Food and Drug Administration (FDA) as an outsourcing facility under section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 353b][1] on May 29, 2015, and reregistered most recently on November 29, 2021. From September 21, 2021 to November 4, 2021, FDA investigators inspected your facility that was acquired by Sagent Pharmaceuticals, Inc., SterRx, LLC, located at 141 Idaho Avenue, Plattsburgh, NY 12903. During the inspection, the investigators noted serious deficiencies in your practices for producing drug products intended or expected to be sterile, which put patients at risk.

FDA issued a Form FDA 483 to your facility on November 4, 2021, and an amended Form FDA 483 on December 1, 2021. FDA acknowledges receipt of your facility's responses, including correspondence dated November 23, 2021, January 31, 2022, March 31, 2022, and June 30, 2022. FDA also acknowledges that your firm voluntarily ceased "production and distribution of all aseptically processed products" as of October 5, 2021. In addition, we acknowledge that on November 12, 2021, your firm initiated a voluntary recall of approximately 240 lots of certain

[1] *See* Pub. L. No. 113-54, § 102(a), 127 Stat. 587, 587-588 (2013).

drug products intended to be sterile that were within expiry due to a lack of sterility assurance. Furthermore, FDA acknowledges your firm's February 4, 2022 "45-day Notification of Intent to Resume Distribution" of sterile products on or after March 21, 2022 and your firm's commitment to destroy 36 in-process lots pursuant to a teleconference held on March 21, 2022. Based on this inspection, it appears you produced drugs that violate the FDCA.

**A. Compounded Drug Products under the FDCA**

Under section 503B(b) of the FDCA, a compounder can register as an outsourcing facility with FDA. Drug products compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility qualify for exemptions from the drug approval requirements in section 505 of the FDCA [21 U.S.C. § 355(a)], the requirement in section 502(f)(1) of the FDCA [21 U.S.C. § 352(f)(1)] that labeling bear adequate directions for use and the Drug Supply Chain Security Act requirements in section 582 of the FDCA [21 U.S.C. § 360eee-1] if the conditions in section 503B of the FDCA are met.[2]

An outsourcing facility, which is defined in section 503B(d)(4) of the FDCA [21 U.S.C. § 353b(d)(4)], is a facility at one geographic location or address that — (i) is engaged in the compounding of sterile drugs; (ii) has elected to register as an outsourcing facility; and (iii) complies with all of the requirements of this section. Outsourcing facilities must comply with other applicable provisions of the FDCA, including section 501(a)(2)(B) [21 U.S.C. § 351(a)(2)(B)], regarding current good manufacturing practice (CGMP), and section 501(a)(2)(A) [21 U.S.C. § 351(a)(2)(A)], regarding insanitary conditions. Generally, CGMP requirements for the preparation of drug products are established in Title 21 of the Code of Federal Regulations (CFR) parts 210 and 211.

**C. Violations of the FDCA**

**Adulterated Drug Products**

FDA investigators noted that drug products intended or expected to be sterile were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health, causing your drug products to be adulterated under section 501(a)(2)(A) of the FDCA. For example, the investigators observed that:

1. Your facility is designed and operated in a way that first air is either not provided or blocked within ISO 5 areas where critical in-process operations are performed. For example:
    a. Lack of first pass air over unwrapped, open IV bags prior to filling.

---

[2] We remind you that there are conditions, other than those discussed in this letter, that must be satisfied to qualify for the exemptions in section 503B of the FDCA.

b. Blocked first pass air for exposed sterile closures (ports and syringe plungers) during introduction and conveyance on IV bag filling lines.

2. Your smoke studies demonstrated that the air in an ISO 5 classified zone was turbulent and non-laminar near areas where IV bag filling and sealing are performed.

3. You did not perform adequate product evaluation and take appropriate corrective action after microbial contamination was recovered within the ISO 5 aseptic processing area.

4. Your firm does not maintain the sterility of inter seals and outer closures for IV bags during production. Blow Fill Seal (BFS) IV bags and caps with ports are exposed to worse than ISO 5 quality air prior to and during assembly/capping.

5. The ISO-classified areas had visibly dirty equipment and difficult to clean surfaces. Specifically, chipped and missing paint, apparent rust, adhesive tape, and a build-up of residues were observed on and around BFS equipment in an area where parisons are cut and conveyed to the point of aseptic filling.

6. Sterilized equipment and utensils wrapped in aluminum foil and tape were stored in your "transition area," an unclassified area, without an established hold time to ensure that these items remain sterile.

FDA investigators also noted CGMP violations at your facility, that caused your drug product(s) to be adulterated within the meaning of section 501(a)(2)(B) of the FDCA. The violations include, for example:

1. Your firm failed to establish an adequate air supply filtered through high-efficiency particulate air filters under positive pressure in the aseptic processing areas (21 CFR 211.42(c)(10)(iii)).

2. Your firm failed to establish an adequate system for monitoring environmental conditions in aseptic processing areas (21 CFR 211.42(c)(10)(iv)).

3. Your firm failed to ensure container closure systems provide protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product (21 CFR 211.94(b)).

4. Your firm failed to use equipment in the manufacture, processing, packing, or holding of drug products that is of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance (21 CFR 211.63).

5. Your firm failed to ensure that substances required for equipment operations, such as lubricants and coolants, do not come in contact with components, drug product

containers, closures, in-process materials, or drug products so as to alter the safety, identity, strength, quality or purity of the drug product beyond the official or other established requirements (211.65(b)).

6. Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed (21 CFR 211.192).

7. Your firm failed to clean, maintain, and, as appropriate for the nature of the drug, sanitize and/or sterilize equipment and utensils at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements (21 CFR 211.67(a)).

8. Your firm failed to establish and follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, and that include validation of all aseptic and sterilization processes (21 CFR 211.113(b)).

Outsourcing facilities must comply with CGMP requirements under section 501(a)(2)(B) of the FDCA. FDA's regulations regarding CGMP requirements for the preparation of drug products have been established in 21 CFR parts 210 and 211. FDA intends to promulgate more specific CGMP regulations for outsourcing facilities. FDA has issued a revised draft guidance, *Current Good Manufacturing Practice — Guidance for Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act.* This draft guidance, when finalized, will describe FDA's expectations regarding outsourcing facilities and the CGMP requirements in 21 CFR parts 210 and 211 until more specific CGMP regulations for outsourcing facilities are promulgated.

Under section 301(a) of the FDCA [21 U.S.C. § 331(a)], the introduction or delivery for introduction into interstate commerce of any drug that is adulterated is a prohibited act. Further, it is a prohibited act under section 301(k) of the FDCA [21 U.S.C. § 331(k)] to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being adulterated.

**D. Corrective Actions**

We have reviewed your facility's responses to the Form FDA 483. FDA acknowledges that your firm voluntarily ceased "production and distribution of all aseptically processed products" as of October 5, 2021, and that your firm intended to resume distribution of sterile products on or after March 21, 2022. We also acknowledge that on November 12, 2021, your firm initiated a voluntary recall of certain lots of drug products intended to be sterile that were within expiry due to a lack of sterility assurance. In addition, we acknowledge that your firm voluntarily destroyed seven (7) in-process lots in March 2022 and one (1) in-process lot on May 2, 2022. Furthermore,

FDA acknowledges your "intent to continue [the voluntary destruction] process with the remaining 28 WIP lots within inventory..."

We are unable to fully evaluate some of your corrective actions due to lack of adequate supporting documentation. For example:

1. In response to Observation 1 of the Form FDA 483, you stated in part: new smoke studies will be performed; environmental monitoring for particles will be revised; BFS machinery and surrounding barriers will be assessed; integrity testing (leak check test) will be performed, equipment that remains in use will be relocated to ensure first pass air is not blocked; and employee training will be provided to include operator prevention of obstructing first pass air. However, you did not provide:

    a. CMTs 2021-424, 2021-426, 2021-427, 2021-428, 2021-429, 2021-430, and 2021-431 referenced in your response pertaining to new smoke studies, changes to particle monitoring, equipment and barrier assessment, leak check testing, and operator training.
    b. Change controls 2021-109 and 2021-110 referenced in your response pertaining to decommissioning of filling lines, installation of new particle monitoring equipment, and environmental monitoring revisions.

2. In response to Observation 2 of the Form FDA 483, you provided a written risk assessment for capping of BFS IV bags and a study evaluating the sterility of caps. However, you did not provide any supporting documentation, such as air certification reports, to demonstrate that the caps and bags are not exposed to worse than ISO 5 quality air during loading, conveying, and capping.

3. In response to Observation 3 of the Form FDA 483, you stated in part: limits for the ISO 5 zones will be changed to 1 CFU and require an investigation; environmental monitoring limits will be standardized to metric units; and the entire environmental monitoring program will be evaluated. Additionally, your response stated continuous particle counting will be implemented and a probe will be added in close proximity to the vibratory bowl. However, you did not provide:

    a. CMTs 2021-435 and 2021-436 referenced in your response pertaining to your environmental monitoring evaluation, revised procedures for ISO 5 zones, and changes to particle monitoring.
    b. Completed document change controls DCC-002749 and DCC-003733 referenced in your response pertaining to revised viable action limits.

4. In response to Observation 4 of the Form FDA 483, you stated in part: the bag filling line would be decommissioned and a new corporate policy, PQL-QA-0025 will be implemented to ensure equipment is adequate for GMP processes. However, you did not provide a copy of PQL-QA-0025 or CMT 2021-444 referenced in your response for

policy implementation and employee training.

5. In response to Observation 5 of the Form FDA 483, you stated in part: the bag filling line would be decommissioned; an assessment would be performed for all product contact lubricants; and SOP-VAL-0103, Equipment/Utility and Software Validation/Qualification, would be revised to include a requirement to assess lubricants as part of equipment qualification. However, you did not provide a copy of the revised SOP-VAL-0103 or CMTs 2021-438 and 2021-439 referenced in your response for SOP revisions and employee training.

6. In response to Observation 6 of the Form FDA 483, you stated in part: the site will transition to compliance software for non-conformances and CAPAs; enhanced training for aseptic techniques and investigations will be developed; and SOP-QA-0157, Manufacturing Investigation Procedure, will be revised. However, you did not provide:

    a. CMT 2021-414 referenced in your response pertaining to your changes to investigations, CAPAs, and related training.
    b. A copy of SOP-QA-0157.

7. In response to Observation 7 of the Form FDA 483, you stated in part: SOP-VAL-0103, Equipment/Utility and Software Validation/Qualification, will be revised and employee training will be conducted. However, you did not provide a copy of SOP-VAL-0103 or CMT 2021-439 referenced in your response for SOP revisions and employee training.

8. In response to Observation 8 of the Form FDA 483, you stated in part: revisions will be made to SOP-P-0435, Operation and Maintenance of the Resin Delivery System. However, you did not provide a copy of SOP-P-0435 or CMT 2021-411 referenced in your response. Additionally, you did not provide supporting documentation referenced in the attachment identified as MEMO-VAL-0037 including but not limited to third-party studies for the lethality of the BFS polymer extrusion process.

In addition to the issues discussed above, you should note that CGMP requires the implementation of quality oversight and controls over the manufacture of drugs, including the safety of raw materials, materials used in drug manufacturing, and finished drug products. *See* section 501 of the FDCA. If you choose to contract with a laboratory to perform some functions required by CGMP, it is essential that you select a qualified contractor and that you maintain sufficient oversight of the contractor's operations to ensure that it is fully CGMP compliant. Regardless of whether you rely on a contract facility, you are responsible for assuring that drugs you produce are neither adulterated nor misbranded. [*See* 21 CFR 210.1(b), 21 CFR 200.10(b).]

FDA strongly recommends that your management undertake a comprehensive assessment of operations, including facility design, procedures, personnel, processes, maintenance, materials, and systems. In particular, this review should assess your aseptic processing operations. We also

recommend a third-party consultant with relevant sterile drug manufacturing expertise to assist you in conducting this comprehensive evaluation.

**E. Conclusion**

The violations cited in this letter are not intended to be an all-inclusive statement of violations at your facility. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

You should take prompt action to address any violations. Failure to adequately address any violations may result in legal action without further notice, including, without limitation, seizure and injunction.

Within fifteen (15) working days of receipt of this letter, please notify this office in writing of the specific steps you have taken to address any violations, or you may inform us that you do not intend to resume production of drugs intended or expected to be sterile. This letter notifies you of our concerns and provides you an opportunity to address them. If you believe your products are not in violation of the FDCA, include your reasoning and any supporting information for our consideration. If you cannot completely address this matter within fifteen (15) working days, state the reason for the delay and the time within which you will do so.

Send your electronic reply to ORAPHARM1_RESPONSES@fda.hhs.gov. Your written notification should refer to Warning Letter #636636 and include FEI: 3010840309.

If you have questions regarding the contents of this letter, please contact Nancy Espinal, Compliance Officer, at Nancy.Espinal@fda.hhs.gov.

Sincerely,

Nerizza B. Guerin -S Digitally signed by Nerizza B. Guerin -S
Date: 2022.07.18 16:42:06 -04'00'

Nerizza Guerin
Acting Program Division Director/District Director
Office of Pharmaceutical Quality Operations
Division I/New Jersey District

SterRx® FDA-Registered 503B Outsourcing Facility

SterRx, LLC
141 IDAHO AVENUE
PLATTSBURGH, NY 12903
844.319.7799

**RESPONSE TO WARNING LETTER**

October 31, 2022

Ms. Nerizza Guerin
Acting Program Division Director/District Director
New Jersey District
Office of Pharmaceutical Quality Operations Division I
U.S. Food and Drug Administration
10 Waterview Blvd, 3rd FL
Parsippany, NJ 07054
ORAPHARM1_RESPONSES@fda.hhs.gov

Re: Response to Warning Letter #636636 for 503B Outsourcing Facility
SterRx, LLC, Plattsburgh, NY (F.E.I. #3010840309), October Update

Dear Ms. Guerin:

SterRx, LLC (SterRx), a majority-owned subsidiary of Sagent Pharmaceuticals, Inc. (Sagent), has prepared the attached updated response to the original Warning Letter #636636 dated July 18, 2022 response provided on 08 August 2022. The Warning Letter resulted from FDA's inspection of SterRx LLC from September 21, 2021 to November 04, 2021.

SterRx understands the significance of FDA's Warning Letter. As an FDA-registered section 503B outsourcing facility, SterRx and Sagent take seriously the responsibility to ensure stringent aseptic processes and practices are in place throughout the facility and comply with FDA's current good manufacturing practice (CGMP) requirements as applied to outsourcing facilities for sterile products.

SterRx and Sagent are committed to continuing to improve our quality systems in a comprehensive manner, to close out the July 18, 2022, FDA Warning Letter.

If you have any questions, please contact Sarah McCoy, Sarah.McCoy@sterrx.com at 518-324-7879 Ext. 1219.

Sincerely,

Electronically signed by: Sarah McCoy
Reason: I have read and approve.
Date: Oct 31, 2022 13:13 EDT

Sarah J. McCoy
Director, Plant Operations
For SterRx, LLC

Electronically signed by: James Horger
Reason: I have read and approve.
Date: Oct 31, 2022 12:18 CDT

James F. Horger
Vice President, Quality & Regulatory Compliance
For Sagent Pharmaceuticals, Inc.

cc: Peter A. Kaemmerer, CEO, Sagent Pharmaceuticals, Inc.

Confidential

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**SterRx, LLC**
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Jerry Webb, EVP, Global Operations, Sagent Pharmaceuticals, Inc.
Kelly Sullivan, Inspector, Pharmacy Consultant, Office of Professional Discipline, New York State Education Department

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**RESPONSE TO WARNING LETTER #636636**

**RESPONSE:** General items

As stated during the inspection, in our FDA 483 and WL responses, as part of the integration into Sagent Pharmaceuticals, SterRx was in the process of implementing changes to facilities, utilities, and equipment. This includes the following:

- Two new IV bag filler lines were scheduled for installation and qualification:
    - A new IV Bag Filler Line E0655 was qualified on 20 Apr 2022.
    - Due to production capacity currently being fulfilled with the first IV Bag Filler Line, the second IV Bag Filler Line E0670 that was scheduled to be qualified in September 2022 has been postponed to Q1 2023.
- Two new labelers have been qualified for Blow Fill Seal BFS 321 bottles and all pouch labeling completed 15 September 2022. This improvement has eliminated manual labeling.
- The Maintenance System (Fluke eMaint Computerized Maintenance Management System (CMMS)) software was implemented on 27 September 2022. This improvement replaces a paper-based system.
- A new 60,000 sq. ft. warehouse located on Connecticut Rd., Plattsburgh, NY has been constructed, and SterRx gained occupancy of this leased warehouse on 22 Aug 2022. Upon approval by the New York State Board of Pharmacy, the new warehouse activities will include the following:
    - Incoming Receiving area.
    - Relocation of support staff for warehouse activities and general office space.
    - Distribution process using JD Edwards Enterprise ERP system for distribution of Finished Product to hospitals (excluding Controlled Substances).
    - Finished Product that is a Controlled Substance will continue to be distributed from the main SterRx facility located at 141 Idaho Avenue.

SterRx resolution of FDA 483 and Warning Letter observations have been supplemented with the ongoing engagement of RCA consultants. We have also engaged two additional independent consulting firms with significant expertise in aseptic processing, 503B Outsourcing Facility compounding, and training to help provide additional system assessments and training.

- Regulatory Compliance Associates Inc. (RCA) performed a comprehensive assessment of operations, facility design, procedures, personnel, processes, maintenance, materials and systems. The RCA Assessment consisted of three separate weeks and was completed on 14 October 2022. The assessment highlighted areas for continuous improvement and opportunities to expand the current updated processes and procedures related to corrective actions in response to the FDA 483 (November 2021) and FDA Warning Letter (July 2022). The assessment had zero critical observations. SterRx is in-process of implementing an action plan to address the findings of the RCA Assessment with a target for approval of the RCA Action Plan on or before 15 November 2022.

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- Compliance Insight provided additional Aseptic Processing Training to Operations, Quality, Engineering, Microbiology, Pharmacy, Materials Management, and Senior Management staff. The training was completed on 19-21 September 2022. See attached training documentation.
- Amicus GMP Consulting, Kristopher Le, Pharm.D. and Becca Mitchell, PharmD performed a comprehensive assessment of 503B Compounding requirements and procedures. The Amicus GMP assessment was completed 03 October 2022. The assessment stated there were zero critical deficiencies noted during the assessment of SterRx's readiness for a follow-up inspection from FDA to its previous inspection in November 2021. The audit focused on the 503B production facility and aseptic processing procedures.

  The recent corrective actions performed in response to the November 2021 Form 483 and subsequent voluntary shutdown and recall represented positive steps toward regulatory compliance. SterRx is in-process of implementing an action plan to address the findings of the Amicus Assessment with a target for approval of the Amicus GMP Action Plan on or before 15 November 2022.

The results from the consulting activity have been reviewed by SterRx and Sagent Pharmaceuticals executive management.

**Training:** Additional training oversight was started on 25 Jul 2022, with the SterRx Production Supervisor who has been assigned a three-month assignment for monitoring production sanitization, room and equipment setup, and aseptic production behavior. The Production Supervisor has been providing updates to SterRx management on the effectiveness of the training provided to operators on aseptic techniques approximately every two weeks during this timeframe. A CAPA record in Trackwise PR 41105 has been closed on 28 October 2022. See the attached Trackwise PR 41105.

**Fentanyl Recall:** During the inspection of Fentanyl stability samples from the first two PPQ batches it was noted a room temperature sample was leaking. This SterRx stability testing observation was on 15 Jun 22. The investigation was conducted, and distribution of Product was halted and product inventory was placed in quarantine pending resolution on 22 Jun 22. The root cause identified was an incomplete seal on the filling port. The IV bag is aseptically filled and then the bag is sealed. Due to leaking IV bags noted during an additional AQL inspection, both lots were recalled.

Recall RES# 90653
Recall Number: D-1331-2022 FentaNYL Citrate in 0.9% Sodium Chloride 1 mg per 100 mL (10 mcg per mL) IV bags Lot CHI.
Recall Number: D-1332-2022 FentaNYL Citrate in 0.9% Sodium Chloride, 2.5 mg per 250 mL, (10 mcg per mL) IV bags Lot CHL

No product complaints or adverse events have been reported for these lots to-date. All customers affected by this recall have been notified and have responded/returned recalled product as of 28 Sep 2022.

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**Syringe Line Decommissioned:** As part of the decommissioning of equipment, SterRx has further evaluated the use of the SterRx Syringe Line in Fill Room 5. Due to market demand, it was determined the best path forward was to decommission Syringe Line. The Syringe line was taken out of service on 30 Jun 2022.

SterRx and Sagent Pharmaceuticals are fully committed to the resolution and close out of the July 18, 2022, FDA Warning Letter. Below is a summary of the status of our FDA 483 activities since November 2021 and commitments in the August 2022 Response to WL:

**Table 1. Status of Corrective Action Activities at SterRx**

| WL# | Obs # | Item | Status |
|---|---|---|---|
| 1 | 1 | In response to Observation 1 of the Form FDA 483, you stated in part: new smoke studies will be performed; environmental monitoring for particles will be revised; BFS machinery and surrounding barriers will be assessed; integrity testing (leak check test) will be performed, equipment that remains in use will be relocated to ensure first pass air is not blocked; and employee training will be provided to include operator prevention of obstructing first pass air. However, you did not provide:<br><br>a. CMTs 2021-424, 2021-426, 2021-427, 2021-428, 2021-429, 2021-430, and 2021-431 referenced in your response pertaining to new smoke studies, changes to particle monitoring, equipment and barrier assessment, leak check testing, and operator training.<br><br>b. Change controls 2021-109 and 2021-110 referenced in your response pertaining to decommissioning of filling lines, installation of new particle monitoring equipment, and environmental monitoring revisions. | **This work has been completed and supporting documentation was provided on 08 August 2022** |
| 2 | 2 | In response to Observation 2 of the Form FDA 483, you provided a written risk assessment for capping of BFS IV bags and a study evaluating the sterility of caps. However, you did not provide any supporting documentation, such as air certification reports, to demonstrate that the caps and bags are not exposed to worse than ISO 5 quality air during loading, conveying, and capping. | **This work has been completed and supporting documentation was provided on 08 August 2022** |

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| WL# | Obs # | Item | Status |
|---|---|---|---|
| 3 | 3 | In response to Observation 3 of the Form FDA 483, you stated in part: limits for the ISO 5 zones will be changed to 1 CFU and require an investigation; environmental monitoring limits will be standardized to metric units; and the entire environmental monitoring program will be evaluated. Additionally, your response stated continuous particle counting will be implemented and a probe will be added in close proximity to the vibratory bowl. However, you did not provide:<br>a. CMTs 2021-435 and 2021-436 referenced in your response pertaining to your environmental monitoring evaluation, revised procedures for ISO 5 zones, and changes to particle monitoring.<br>b. Completed document change controls DCC-002749 and DCC-003733 referenced in your response pertaining to revised viable action limits. | **This work has been completed and supporting documentation was provided on 08 August 2022** |
| 4 | 4 | In response to Observation 4 of the Form FDA 483, you stated in part: the bag filling line would be decommissioned and a new corporate policy, PQL-QA-0025 will be implemented to ensure equipment is adequate for GMP processes. However, you did not provide a copy of PQL-QA-0025 or CMT 2021-444 referenced in your response for policy implementation and employee training. | **This work has been completed and supporting documentation was provided on 08 August 2022** |
| 5 | 5 | In response to Observation 5 of the Form FDA 483, you stated in part: the bag filling line would be decommissioned; an assessment would be performed for all product contact lubricants; and SOP-VAL-0103, Equipment/Utility and Software Validation/Qualification, would be revised to include a requirement to assess lubricants as part of equipment qualification. However, you did not provide a copy of the revised SOP-VAL-0103 or CMTs 2021-438 and 2021-439 referenced in your response for SOP revisions and employee training. | **This work has been completed and supporting documentation was provided on 08 August 2022. The IV Bag Filling line was removed from the SterRx facility on 12 Aug 2022** |
| 6 | 6 | In response to Observation 6 of the Form FDA 483, you stated in part: the site will transition to compliance software for non-conformances and CAPAs; enhanced training for aseptic techniques and investigations will be developed; and SOP-QA-0157, Manufacturing Investigation Procedure, will be revised. However, you did not provide: | **This work has been completed and supporting documentation was provided on 08 August 2022** |

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PLATTSBURGH, NY 12903
844.319.7799

| WL# | Obs # | Item | Status |
|---|---|---|---|
| | | a. CMT 2021-414 referenced in your response pertaining to your changes to investigations, CAPAs, and related training.<br>b. A copy of SOP-QA-0157. | |
| 7 | 7 | In response to Observation 7 of the Form FDA 483, you stated in part: SOP-VAL-0103, Equipment/Utility and Software Validation/Qualification, will be revised and employee training will be conducted. However, you did not provide a copy of SOP-VAL-0103 or CMT 2021-439 referenced in your response for SOP revisions and employee training. | **This work has been completed and supporting documentation was provided on 08 August 2022** |
| 8 | 8 | In response to Observation 8 of the Form FDA 483, you stated in part: revisions will be made to SOP-P-0435, Operation and Maintenance of the Resin Delivery System. However, you did not provide a copy of SOP-P-0435 or CMT 2021-411 referenced in your response. Additionally, you did not provide supporting documentation referenced in the attachment identified as MEMO-VAL-0037 including but not limited to third-party studies for the lethality of the BFS polymer extrusion process. | **This work has been completed and supporting documentation was provided on 08 August 2022** |

**Attachments:**

1. Compliance Insight Training documentation
2. CAPA record in Trackwise PR 41105
3. Change Control CC-2022-055 for removal of IV Bag Filling Line.

**STERRX, LLC**

GENERAL INFO | ENFORCEMENT ACTIONS

| | |
|---|---|
| **Type** | Outsource Facility |
| **Legal Name** | STERRX, LLC |
| **Trade Name** | --- |
| **Street Address** | 141 IDAHO AVENUE<br>PLATTSBURGH NY 12903 |
| **Registration No** | 034102 |
| **Date First Registered** | March 14, 2016 |
| **Registration Begins** | March 01, 2022 |
| **Registered Through** | February 28, 2025 |
| **Supervisor** | 056883 - DOMINY THOMAS JOSEPH |
| **Establishment Status** | Active |
| **Successor** | NONE |

March 29, 2023 10:15 AM (ET)

https://www.op.nysed.gov/verification-search?pharmacyRegistrationNumber=034102&professionCode=020

**STERRX, LLC**

X

GENERAL INFO | ENFORCEMENT ACTIONS

**Registration No:** 034102

No Enforcement Actions Found

March 29, 2023 10:15 AM (ET)

https://www.op.nysed.gov/verification-search?pharmacyRegistrationNumber=034102&professionCode=020

| | | | | | | |
|---|---|---|---|---|---|---|
| SSM Health Care Corporation, Fenton, MO | Melissa Mays 636-496-2681 | 2/18/2014 | 12/5/2022 | 9/28/2021 | Yes (https://www.fda.gov/media/155226/download) | Open[7] |
| STAQ Pharma, Inc., Denver, CO | Joe Bagan 303-810-6777 | 2/5/2019 | 12/28/2022 | 9/29/2021 | Yes (https://www.fda.gov/media/158588/download) | FMD-145 Letter Issued 3/25/2022 |
| STAQ Pharma of Ohio, LLC, Columbus, OH | Joe Bagan 303-810-6777 | 1/26/2023 | 1/25/2023 | Not yet inspected | No | N/A |
| Staska Pharmaceuticals, Inc., Bennet, NE | Lyndon Leitner 402-782-2207 | 12/3/2020 | 12/22/2022 | Not yet inspected | N/A | N/A |
| SterRx LLC, Plattsburgh, NY | Thomas J. Dominy 518-324-7879 Ext=1249 | 5/29/2015 | 10/31/2022 | 11/4/2021 | Yes (/media/156608/download) | Open[7] |
| Stokes Healthcare Inc., dba Epicur Pharma, Mt. Laurel, NJ | Michael Tursi 888-508-5032 | 1/30/2018 | 10/28/2022 | 10/9/2020 | Yes (https://www.fda.gov/media/144723/download) | Untitled Letter Issued 5/2/2022 |
| Tailstorm Health Inc., Chandler, AZ | Andrew Stasiak 520-465-8496 | 10/23/2019 | 12/10/2022 | 7/21/2021 | Yes (https://www.fda.gov/media/155218/download) | Untitled Letter Issued 6/17/2022 (https://www.fda.gov/media/163521/download) |
| Tailstorm Health Inc., Phoenix, AZ | Mitexh Gandhi 480-274-8617 | 10/23/2019 | 2/8/2023 | Not yet inspected | No | N/A |
| The Ritedose Corporation, Columbia, SC | Arianne Lindsey 803-626-3737 | 12/20/2019 | 10/28/2022 | 3/22/2022 | Yes (https://www.fda.gov/media/159209/download) | FMD-145 Letter Issued 9/23/2022 |
| US Specialty Formulations LLC, Allentown, PA | Kyle Flanigan 610-849-5023 | 1/31/2014 | 11/22/2022 | 4/26/2022 | Yes (https://www.fda.gov/media/160666/download) | Open[7] |
| Wedgewood Connect, LLC, formerly registered as Leiter's Compounding, San Jose, CA | Paul Yamamoto 408-687-0943 | 1/31/2014 | 12/5/2022 | 12/3/2021 | Yes (https://www.fda.gov/media/157736/download) | FMD-145 Letter Issued 4/29/2022 |
| Wells Pharma of Houston, LLC, Houston, TX | Theaquiata A. Mitchell 346-888-1010 Ext=4811 | 3/9/2020 | 12/15/2022 | 6/17/2021 | Yes (https://www.fda.gov/media/155873/download) | FMD-145 issued 1/10/2022 |
| Wells Pharmacy, Inc., Dyersburg, TN | Melissa Stefko 800-622-4510 | 6/7/2016 | 12/13/2022 | 1/28/2021 | Yes (https://www.fda.gov/media/147184/download) | Untitled Letter Issued 5/19/2022 (https://www.fda.gov/media/163363/download) |

## Notes

1. The "initial date of registration as an outsourcing facility" is the date the facility was first registered (i.e., the date FDA determined that the initial registration information submitted for the facility was complete, and for firms first registering on or after October 1, 2014, the establishment fee was paid in full).

Under section 503B(b) of the FD&C Act, after the initial registration, a facility that elects to continue to be registered with FDA as an outsourcing facility must re-register annually. Beginning in fiscal year (FY) 2015 (October 1, 2014 to September 30, 2015), a facility that elects to register (or re-register) with FDA as an outsourcing facility must pay an annual establishment fee. The "date of most recent registration as an outsourcing facility" reflects the date FDA determined the most recently submitted registration information was complete and the annual establishment fee for that fiscal year paid in full.

Top ()

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**FOOD AND DRUG ADMINISTRATION**

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 158-15 Liberty Avenue<br>Jamaica, NY 11433<br>(718) 340-7000 Ext:5301 Fax: (718)662-5661<br>ORAPHARM1_RESPONSES@fda.hhs.gov | 9/21/2021-11/4/2021* |
| | FEI NUMBER<br>3010840309 |

| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | |
|---|---|
| Sarah J. McCoy, Director, Plant Operations | |
| FIRM NAME<br>SterRx, LLC | STREET ADDRESS<br>141 Idaho Ave |
| CITY, STATE, ZIP CODE, COUNTRY<br>Plattsburgh, NY 12903-3987 | TYPE ESTABLISHMENT INSPECTED<br>Outsourcing Facility 503B |

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:**

## OBSERVATION 1

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under (b) (4) pressure.

Specifically:

1. Blow-Fill-Seal (BFS) operations in you(b) (4) process, including (b) (4) and shuttling of the (b) (4) to the point of aseptic filling, are conducted under air supplied at lesser quality than ISO 5. (b) (4) are exposed during (b) (4) and shuttling within the ISO 7 classified zone to the point of aseptic filling in BFS machines BFS (b) (4) Equipment # (b) (4) and BFS (b) (4) , Equipment # (b) (4)

   Furthermore, you have not evaluated the airflow pattern and airborne particulates in the critical processing zones during operation of BFS machines BFS (b) (4) and BFS (b) (4) where (b) (4) and the (b) (4) are shuttled to the point of aseptic filling.

   BFS (b) (4) is used to produce drug products intended to be sterile including 20mg Phenylephrine HCl in 0.9% Sodium Chloride Injection, Batch: (b) (4) packaged as Lot: (b) (4), Released: 04/30/2021, Expiration Date: 01/30/2022.

   BFS (b) (4) is used to produce drug products intended to be sterile including Sodium Bicarbonate 150mEq/1000ml in 5% Dextrose Injection, Batch: (b) (4) packaged as Lot: (b) (4), Released: 02/23/2021, Expiration Date: 12/28/2021.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE<br>Edmund F Mrak, Investigator<br>Lori M Newman, Investigator | X | DATE ISSUED<br>11/4/2021 |
|---|---|---|---|

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 158-15 Liberty Avenue<br>Jamaica, NY 11433<br>(718) 340-7000 Ext:5301 Fax:(718)662-5661<br>ORAPHARM1_RESPONSES@fda.hhs.gov | 9/21/2021-11/4/2021* |
| | FEI NUMBER<br>3010840309 |

| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | |
|---|---|
| Sarah J. McCoy, Director, Plant Operations | |
| FIRM NAME<br>SterRx, LLC | STREET ADDRESS<br>141 Idaho Ave |
| CITY, STATE, ZIP CODE, COUNTRY<br>Plattsburgh, NY 12903-3987 | TYPE ESTABLISHMENT INSPECTED<br>Outsourcing Facility 503B |

2. The design and construction of the IV Bag filling line, Equipment # (b) (4) and its enclosure do not provide first pass HEPA-filtered laminar flow air over all critical areas within the ISO 5 classified zone as follows:

   a. Your dynamic airflow pattern study conducted under protocol PR-2018-187(b) (4) and reported in RPT-2018-187-(b) (4) Bag Filling and Sealing Machine (b) (4) Smoke Study, identified turbulence and upward flow of air near Fill Station (b) (4) This airflow condition was accepted and approved on 10/15/2019 by your firm management without attempting corrective actions.

   b. Direct coverage by first pass HEPA-filtered laminar flow air is not provided over the filling side of the (b) (4) Bag Filling and Sealing Machine where open IV bags are (b) (4) removed from wrapping and exposed, held, and passed to the filling section of the line.

   c. First pass HEPA-filtered laminar flow air is blocked by the "(b) (4) " over approximately one half of the (b) (4) bowl and the track system (b) (4) to the filling side of the (b) (4) Bag Filling and Sealing Machine. Furthermore, your airflow pattern study reported in RPT-2018-187-(b) (4) Bag Filling and Sealing Machine (b) (4) Smoke Study, did not evaluate the airflow pattern in the area of the (b) (4) bowl and track system where it is obstructed by the (b) (4) .

   The IV Bag filling line, Equipment # (b) (4) is used to produce drug products intended to be sterile including Midazolam 1 mg/ml in 0.9% Sodium Chloride, 100ml fill in 100ml IV Bag, Batch: (b) (4) packaged as Lot: (b) (4), Released: 05/07/2021, Expiration Date: 11/19/2021.

3. First pass HEPA-filtered laminar flow air is obstructed by the (b) (4) and (b) (4) and the (b) (4) bowl over open, partial bags of syringe plungers held adjacent to the (b) (4) bowl

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE<br>Edmund F Mrak, Investigator<br>Lori M Newman, Investigator | X | DATE ISSUED<br>11/4/2021 |
|---|---|---|---|

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 158-15 Liberty Avenue<br>Jamaica, NY 11433<br>(718) 340-7000 Ext:5301 Fax:(718)662-5661<br>ORAPHARM1_RESPONSES@fda.hhs.gov | 9/21/2021-11/4/2021* |
| | FEI NUMBER<br>3010840309 |

| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | |
|---|---|
| Sarah J. McCoy, Director, Plant Operations | |
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used to hold and convey plungers on the aseptic syringe filling system (b) (4)

Equipment # (b) (4) The (b) (4)

, Equipment # (b) (4), is used to produce drug products intended to be sterile including 200 mg Succinylcholine Chloride Injection 10mL (20 mg/mL), Batch: (b) (4) filled on 09/24/2021.

**OBSERVATION 2**

Container closure systems do not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.

Specifically:

You do not maintain the sterility of the cap and bag interfacing surfaces and the interstitial space making up the container closure of BFS IV bags containing sterile drug products. Furthermore, the container closure is not designed such that the user can sanitize the surface(s) before spiking for administration to a patient. More specifically:

1. The cap and bag interfacing surfaces and the interstitial space making up the container closure of BFS IV bags containing drug products produced in BFS (b) (4) Equipment # (b) (4) are not maintained sterile. Filled BFS IV bags produced in BFS (b) (4) are (b) (4) offloaded from a conveyor and held in an ISO 7 classified area prior to capping. The capping process includes sanitization of the BFS IV bag tops with (b) (4)
(b) (4)
(b) (4) , before capping under ISO 7 conditions. BFS (b) (4) and the offline capping system are used to produce drug products intended to be sterile including 20mg Phenylephrine HCl in 0.9% Sodium Chloride Injection,

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Batch: (b) (4) packaged as Lot: (b) (4), Released: 04/30/2021, Expiration Date: 01/30/2022.

2. The cap and bag interfacing surfaces and the interstitial space making up the container closure of BFS IV bags containing drug products produced in BFS (b) (4) , Equipment # (b) (4) are not maintained sterile and are exposed to less than ISO 5 environmental conditions. BFS IV bags containing drug products produced in BFS (b) (4) are conveyed and capped (b) (4) under ISO 7 classified conditions. BFS (b) (4) , Equipment # (b) (4) is used to produce drug products intended to be sterile including Sodium Bicarbonate 150mEq/1000ml in 5% Dextrose Injection, Batch: (b) (4) packaged as Lot: (b) (4), Released: 02/23/2021, Expiration Date: 12/28/2021.

**OBSERVATION 3**

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically:

1. Your surface and airborne viable monitoring program for aseptic filling operations is not designed and conducted to provide meaningful data to support the quality of your drug products intended to be sterile. Your firm's procedures permit surface and air samples from within ISO 5 environments to yield microbiological contaminants of (b) (4) without conducting an investigation. More specifically:

    a. Prior to revision in August 2021 your environmental monitoring plans and specifications for surface viable monitoring permitted (b) (4) microbial recoveries on filling needles and mandrels (BFS) in the critical filling zones of the IV Bag filling line, Equipment # (b) (4) Syringe Line, Equipment # (b) (4) BFS (b) (4) Equipment # (b) (4) and BFS (b) (4) (b) (4) Equipment # (b) (4) without requirements for investigation and action. For example:

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i. Your environmental monitoring plan, Environmental Monitoring – Bag Filler (b) (4) permitted (b) (4) microbial recoveries on filling needles in the critical filling zone of the IV Bag filling line, Equipment # (b) (4) Your environmental monitoring record for filling Midazolam 1 mg/ml in 0.9% Sodium Chloride, 100ml fill in 100ml IV Bag, Batch: (b) (4) Environmental Monitoring Lot: (b) (4) on the IV Bag filling line, Equipment # (b) (4) shows that "Post Batch Bag Filler Sampling – ISO 5" performed on 03/24/2021 recovered (b) (4) from the surface of the right filling needle. You did not investigate or take any other action, and the batch was packaged as Lot: (b) (4), Released: 05/07/2021, Expiration Date: 11/19/2021.

ii. Your environmental monitoring plan, Environmental Monitoring – Syringe Line, permitted (b) (4) microbial recoveries on filling needles in the critical filling zone of the Syringe Line, Equipment # (b) (4) Your environmental monitoring record for filling Succinylcholine 20mg/ml in 0.4% Sodium Chloride – 10ml Pre-Filled Syringe, Batch: (b) (4) , Environmental Monitoring Lot: (b) (4) on the Syringe Line, Equipment # (b) (4) shows that "Post Batch Syringe Line Sampling – ISO 5" performed on 04/06/2020 recovered (b) (4) from the surface of the (b) (4) filling needle. You did not investigate or take any other action, and the batch was packaged as Lot: (b) (4), Released: 05/20/2020, Expiration Date: 07/05/2020.

iii. Your environmental monitoring plans, Environmental Monitoring – ISO 7 (b) (4) and ISO 8 Fill Room (b) (4) ) and Environmental Monitoring – ISO 8 Cleanroom, permitted (b) (4) microbial recoveries on filling mandrels in the critical filling zone of the BFS (b) (4) , Equipment # (b) (4) Your environmental monitoring record for filling Sodium Bicarbonate 150mEq/1000ml

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in 5% Dextrose Injection, Batch: (b) (4) Environmental Monitoring Lot: (b) (4) on the BFS (b) (4) Equipment #(b) (4) shows that "Post Batch BFS (b) (4) Fill Zone Sampling – ISO 5" performed on 04/27/2021 recovered 1 CFU from the surface of the (b) (4) Mandrel From the Front – Left Side. You did not investigate or take any other action, and the batch was packaged as Lot: (b) (4), Released: 05/21/2021, Expiration Date: 03/23/2022.

Additionally, your environmental monitoring record for filling Sodium Bicarbonate 150mEq/1000ml in 5% Dextrose Injection, Batch: (b) (4) Environmental Monitoring Lot: (b) (4) 0 on the BFS (b) (4) , Equipment # (b) (4) shows that "Post Batch BFS (D) (4) Fill Zone Sampling – ISO 5" performed on 01/13/2021 recovered 1 CFU from the surface of the (b) (4) Mandrel – Right Side. You did not investigate or take any other action, and the batch was packaged as Lot: (b) (4), Released: 02/17/2021, Expiration Date: 12/09/2021.

iv. Your environmental monitoring plan, Environmental Monitoring – ISO 7 Cleanroom *with Sanitization* (b) (4) , permitted (b) (4) microbial recoveries on filling mandrels in the critical filling zone of the BFS (b) (4) Equipment # (b) (4). Your environmental monitoring record for filling Norepinephrine 8mg in 0.9% Sodium Chloride Injection-250ml, Batch: (b) (4) Environmental Monitoring Lot: (b) (4) on the BFS (b) (4) Equipment # (b) (4) shows that "Post Batch Fill Zone Sampling – ISO 5" performed on 01/16/2020 recovered 1 CFU from the surface of the (b) (4) Mandrel – (b) (4) . You did not investigate or take any other action, and the batch was packaged as Lot: (b) (4), Released: 04/09/2020, Expiration Date: 08/22/2020.

b. Your current environmental monitoring plans and specifications for airborne and surface viable monitoring permit (b) (4) recoveries within the ISO 5 classified zones inside the enclosures of the IV Bag filling line, Equipment # (b) (4) and Syringe Line, Equipment #

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(b) (4) without requirements for investigation and action. For example:

i. Your Work Instruction WI-MCB-0017 for drug products filled on the IV Bag filling line, Equipment # (b) (4) permits surface and air samples from within ISO 5 environment to yield microbiological contaminants of (b) (4) without investigation and action. For example:

1. Your environmental monitoring record for filling Midazolam 1mg/ml in 0.9% Sodium Chloride, 50ml fill in 100ml IV Bag, Batch: (b) (4) Environmental Monitoring Lot: (b) (4) on the IV Bag filling line, Equipment # (b) (4) shows that "Post Batch Bag Filler Sampling – ISO 5" performed on 04/07/2021 recovered 1 CFU from the surface of the Bag Filler Interior, Filling Side Interior Plexiglass Left. You did not investigate or take any other action, and the batch was packaged as Lot: (b) (4), Released: 05/07/2021, Expiration Date:12/02/2021.

2. Your environmental monitoring record for filling 150 mEq Sodium Bicarbonate in 5% Dextrose Injection, 1000ml, Batch: (b) (4) Environmental Monitoring Lot: (b) (4) on the IV Bag filling line, Equipment # (b) (4) shows that airborne viable monitoring "During the Batch Bag Filler Sampling – ISO 5" performed on 04/23/2020 recovered 1 CFU from the Bag Filler Side. You did not investigate or take any other action, and the batch was packaged as Lot: (b) (4), Released: 05/13/2020, Expiration Date: 03/18/2021.

ii. Your Work Instruction WI-MCB-0012 for drug products filled on the Syringe Line, Equipment # (b) (4) permits surface and air samples from within the ISO 5 environment to yield microbiological contaminants of (b) (4) without investigation

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and action.

c. Your current environmental monitoring plans and specifications for airborne viable monitoring permit (b) (4) recoveries in the critical filling zones of BFS (b) (4) Equipment # (b) (4) and BFS (b) (4) , Equipment # (b) (4) without requirements for investigation and action. For example:

i. Your Work Instruction WI-MCB-0009 for drug products filled on BFS (b) (4) Equipment # (b) (4) permits air samples from within the ISO 5 Fill Zone to yield microbiological contaminants of (b) (4) without investigation and action. For example:

1. Your environmental monitoring record for filling 20mg Phenylephrine HCl in 0.9% Sodium Chloride Injection, Batch: (b) (4) Environmental Monitoring Lot: (b) (4) on the BFS (b) (4) Equipment # (b) (4) shows that airborne viable monitoring "During the Batch Fill Zone Sampling – ISO 5" performed on 04/05/2021 recovered 1 CFU from the Fill Zone (b) (4). You did not investigate or take any other action, and the batch was packaged as Lot: (b) (4), Released: 04/30/2021, Expiration Date: 01/30/2022

ii. Your Work Instruction WI-MCB-0011 for drug products filled on BFS (b) (4) , Equipment # (b) (4) permits air samples from within the ISO 5 Fill Zone to yield microbiological contaminants of (b) (4) without investigation and action. For example:

1. Your environmental monitoring record for filling Sodium Bicarbonate 150mEq/1000ml in 5% Dextrose Injection, Batch: (b) (4) Environmental

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Monitoring Lot: (b) (4) on the BFS (b) (4), Equipment # (b) (4) shows that airborne viable monitoring "Post Batch BFS (b) (4) Fill Zone Sampling – ISO 5" performed on 02/01/2021 recovered 1 CFU from the from the Fill Zone (b) (4). You did not investigate or take any other action, and the batch was packaged as Lot: (b) (4), Released: 02/23/2021, Expiration Date: 12/28/2021.

2. Your airborne particulate monitoring program for aseptic filling operations is not designed and conducted to provide meaningful data to support the quality of your drug products intended to be sterile. You do not monitor airborne particulates to ISO 5 air classifications in all critical locations; the frequency of airborne particulate monitoring is not adequately supported; and the orientation of particle counter probes is not directed into the flow of air in monitored locations. For example:

   a. Airborne particulate monitoring of filling operations on the IV Bag filling line, Equipment # (b) (4) (b) (4) Type (b) (4) does not include all critical locations; the frequency of airborne particulate monitoring is not adequately supported; and the orientation of particle counter probes is not directed into the flow of air in monitored locations. More specifically:

      i. You do not monitor airborne particulates in close proximity to open IV bags that are (b) (4) unwrapped and held for filling.

      ii. You do not provide scientific justification for the frequency of airborne particulate monitoring performed in the filler side and the injection port feed side pre-batch filling (b) (4) according to your Work Instruction WI-MCB-0017.

      iii. The orientation of particle counter probes is not directed into the flow of air in monitored locations near the filler and the port bowl and track.

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Furthermore, your specifications written in Work Instruction WI-MCB-0017 and batch monitoring records for airborne particle counts taken on the filler side of the IV Bag filling line during filling of 150mEq Sodium Bicarbonate in 5% Dextrose Injection and 125mg Diltiazem D5W / 125mg Diltiazem 0.7% Sodium Chloride Injection do not meet clean area air classifications for ISO 5 as follows:

- 150mEq Sodium Bicarbonate in 5% Dextrose Injection:
  - (b) (4) µm Alert ≥ (b) (4) particles/ft³
  - (b) (4) µm Action: ≥ (b) (4) particle/ft³

- 125mg Diltiazem D5W / 125mg Diltiazem 0.7% Sodium Chloride Injection:
  - (b) (4) µm Alert ≥ (b) (4) particle/ft³
  - (b) (4) µm Action (b) (4) particle/ft³

You do not investigate excursions over ISO 5 air classifications that are within your internal specifications shown above. For example: Your environmental monitoring record for filling 125 mg Diltiazem D5W/125mg Diltiazem 0.7% Sodium Chloride, Batch: (b) (4) Environmental Monitoring Lot: (b) (4) on the IV Bag filling line, Equipment # (b) (4) (b) (4) Type (b) (4) shows that "During the Batch Bag Filler Sampling – ISO 5" performed on (b) (4) 06/24/2021 resulted in 160.0 particles/ft³ over (b) (4) µm. This result exceeds limits established in ISO 5 air classifications, but it was deemed acceptable in accordance with your internal specifications and there were no actions taken. The batch was packaged as Lot: (b) (4), Released: 07/28/2021, Expiration Date: 02/19/2022.

b. Airborne particulate monitoring of filling operations on the aseptic syringe filling system,

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(b) (4)
Equipment # (b) (4) does not include all critical locations; the frequency of airborne particulate monitoring is not adequately supported; and the orientation of particle counter probes is not directed into the flow of air in the monitored location. More specifically:

i. You do not monitor airborne particulates in close proximity to the (b) (4) bowl and track.
ii. You do not provide scientific justification for the frequency of airborne particulate monitoring performed in the syringe filling system (b) (4) pre-batch filling (b) (4) according to your Work Instruction WI-MCB-0012.
iii. The orientation of the (b) (4) is not directed into the flow of air in the monitored location near the filler head.

The (b) (4), Equipment # (b) (4) is used to produce drug products intended to be sterile including 200 mg Succinylcholine Chloride Injection 10mL (20 mg/mL), Batch: (b) (4) filled on 09/24/2021.

c. You do not provide scientific justification for the frequency of airborne particulate monitoring performed in the critical filling zone of BFS (b) (4) Equipment # (b) (4) (b) (4) according to your Work Instruction WI-MCB-0009 and batch monitoring records.

Furthermore, your specifications written in Work Instruction WI-MCB-0009 and batch monitoring records for airborne particle count of (b) (4) µm Alert > (b) (4) particles/ft³, Action >

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(b) (4) particles/ ft³, in the critical filling zone of BFS (b) (4) Equipment # (b) (4) do not meet clean area air classifications for ISO 5. No corrective actions are taken for excursions over ISO 5 air classifications that are within your internal specifications. For example: Your environmental monitoring record for filling 4 mg Norepinephrine in 0.9% Sodium Chloride Injection 250 mL (16 mcg/ml) BFS IV Bag, Batch: (b) (4) Environmental Monitoring Lot: (b) (4) in BFS (b) (4) shows that "During the Batch Fill Zone Sampling – ISO 5" initial performed on 09/09/2021 resulted in 359.0 particles/ft³ over (b) (4) µm and the end of batch result was 502.0 particles/ft³ over (b) (4) µm. These results exceed the limits established in Class 100 / ISO 5 air classifications, but they were deemed acceptable in accordance with your internal specifications and there were no actions taken. The batch was packaged as Lot: (b) (4) Released: 09/29/2021, Expiration Date: 09/04/2022.

**OBSERVATION 4**

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its cleaning and maintenance.

Specifically:

The design and construction of BFS (b) (4) Equipment # (b) (4) incorporates machine parts that are particle generating and difficult to sanitize within the ISO 7 classified zone of your (b) (4) process equipment. During the inspection we observed the following within the ISO 7 Classified shrouded area of BFS (b) (4) painted machine parts were chipped and missing paint; the machine frame had signs of surface corrosion; wiring was hanging and secured with tape; tubing was hanging; and there was a build-up of resin residues. Additionally, tubing and wiring are not routed and secured in a manner to prevent chaffing and particle generation. The ISO 7 classified area where these conditions were observed houses the critical processing zone of BFS (b) (4) where (b) (4) are shuttled to the point of aseptic filling. BFS (b) (4) is used to produce drug products intended to be sterile including 20mg

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Phenylephrine HCl in 0.9% Sodium Chloride Injection, Batch (b) (4) , packaged as Lot: (b) (4), Released: 04/30/2021, Expiration Date: 01/30/2022.

**OBSERVATION 5**

Substances required for equipment operations such as lubricants and coolants come in contact with components and closures so as to alter the safety, identity, strength, quality or purity of the drug product beyond the official or other established requirements.

Specifically:

On the IV Bag filling line, Equipment # (b) (4) (b) (4) Type (b) (4) you have not evaluated whether or to what extent solvents and lubricants contained in (b) (4) spray applied to the (b) (4) bowl transfer to and contaminate IV Bag closures (ports). In accordance with your manufacturing batch records, during setup and operation of IV Bag filling line, Equipment # (b) (4) (b) (4) Type (b) (4) you apply (b) (4) spray onto the stainless-steel (b) (4) bowl to (b) (4) . Your manufacturing batch records indicate that the machine may be stopped during the filling operation and "(b) (4) ". The IV Bag filling line, Equipment # (b) (4) is used to produce drug products intended to be sterile including Midazolam 1 mg/ml in 0.9% Sodium Chloride, 100ml fill in 100ml IV Bag, Batch: (b) (4) , packaged as Lot: (b) (4), Released: 05/07/2021, Expiration Date: 11/19/2021.

**OBSERVATION 6**

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There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically:

You lack complete information about the environmental conditions in critical areas during aseptic filling operations necessary for investigation and determination of the full product impact and root cause of environmental excursions and drug product sterility failures. Furthermore, your lack of complete environmental data and root cause identification diminishes your ability to determine and implement effective corrective and preventive actions. For example:

1. Since June 2019 you have reported three drug product sterility failures for lots produced on the IV Bag filling line, Equipment # (b) (4) Conclusions from your investigations are as follows:
   a. Your investigation, MIR-2019-350, for 150mEq Sodium Bicarbonate in 5% Dextrose batch (b) (4) Lot (b) (4), manufactured on (b) (4), out of specification (OOS) results for Particulate Matter per USP<788> and Not Sterile per USP<71>, was inconclusive. Organisms recovered were identified as *Herbaspirillum huttiense* and *Burkholderia multivorans*. The batch was rejected. There was no assignable cause determined and no CAPA initiated. Your investigation failed to attempt identification of the particulate matter in the drug product samples and use such information to assist in determining the root cause of the event and effective CAPA. Your investigation failed to consider whether an inadequate environmental monitoring program for the IV Bag filling line, Equipment # (b) (4) and equipment design deficiencies affecting airflow in critical areas contributed to this event.

   b. Your investigation, MIR-2020-008, for 150mEq Sodium Bicarbonate in 5% Dextrose batch (b) (4) Lot (b) (4), manufactured on (b) (4) OOS result Not Sterile per USP<71>, identified inadequate methods for cleaning and sanitization of the IV Bag filling line following maintenance interventions. The organism recovered was identified as

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| Sarah J. McCoy, Director, Plant Operations | |
| FIRM NAME<br>SterRx, LLC | STREET ADDRESS<br>141 Idaho Ave |
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*Burkholderia multivorans*. The batch was rejected. Your investigation failed to consider whether an inadequate environmental monitoring program for the IV Bag filling line, Equipment # (b) (4) and equipment design deficiencies affecting airflow in critical areas contributed to this event.

c. Your investigation, MIR-2020-127, for 150mEq Sodium Bicarbonate in 5% Dextrose batch (b) (4) Lot (b) (4), manufactured on (b) (4) , OOS result Not Sterile per USP<71>, was inconclusive. The batch was rejected. Although there was no assignable cause attributable to the contract laboratory your investigation concluded that the most likely cause of this event was contamination during testing since the analyst performed (b) (4) tests on the day that the subject sample was tested, and the organism (*Staphylococcus epidermidis*) only grew in one media. Your investigation failed to consider whether an inadequate environmental monitoring program for the IV Bag filling line, Equipment # (b) (4) and equipment design deficiencies affecting airflow in critical areas contributed to this event.

2. Your investigation, MIR-2020-099, for 150mEq Sodium Bicarbonate in 5% Dextrose batch (b) (4) Lot (b) (4), manufactured on BFS (b) (4) Equipment # (b) (4) on 03/18-19/2020, OOS result Not Sterile per USP<71>, was inconclusive. The organism recovered was identified as *Bacillus subtilis*. The batch was rejected. There was no assignable cause determined and no CAPA initiated. Your investigation failed to identify the BFS (b) (4) Equipment # (b) (4) condition and inadequate environmental monitoring program as potentially contributing to this event.

3. Your investigations including MIR-2021-310, MIR-2021-421, and MIR-2021-463 in response to airborne particle count exceeding action limits in the critical zone of the IV Bag filling line, Equipment # (b) (4) conclude that multiple equipment related issues inherent to the filling process on the IV Bag filling line are the root cause of the subject events. You determined that there was no product impact resulting from these events due to acceptable viable monitoring results, visual inspection results, and finished product release testing results and all batches/lots implicated in these

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investigations were released in full. You did not determine and implement effective preventive actions to control generation of particulate contamination within the ISO 5 classified zone of the IV Bag filling line, Equipment # (b) (4) Furthermore, although your records indicate that drug products produced during periods of high particle count generation were segregated by the Packaging Unit, your Quality Unit did not issue a hold status or otherwise control the implicated (segregated) product and require additional consideration for its disposition.

For example:

a. Your investigation, MIR-2021-310, was written for three events of over-action in-process particle counts on the IV Bag filling line, Equipment # (b) (4) during production of drug products as follows:

   i. 0n 06/03/2021, in-process environmental monitoring detected 708.0 particles/ft³ over (b) (4) µm, exceeding the Action Limit: (b) (4) particles/ft³ over (b) (4) µm, on the filling side of the IV Bag filling line, Equipment # (b) (4) while filling 125 mg Diltiazem D5W/125mg Diltiazem 0.7% Sodium Chloride Batch: (b) (4) Lot: (b) (4), Released: 07/14/2021, Expiration Date: 01/28/2022.

   ii. 0n 06/15/2021, in-process environmental monitoring detected 119.0 particles/ft³ over (b) (4) µm, exceeding the Action Limit: ≤ (b) (4) particles/ft³ over (b) (4) µm, on the filling side of the IV Bag filling line, Equipment # (b) (4) while filling 100 mg Morphine Sulfate 1 mg/ml in 5% Dextrose 100 ml, Batch: (b) (4) , Lot: (b) (4), Released: 07/08/2021, Expiration Date: 12/12/2021.

   iii. 0n 06/17/2021, in-process environmental monitoring detected 143.0 particles/ft³ over (b) (4) µm, exceeding the Action Limit: ≤ (b) (4) particles/ft³ over (b) (4) µm, on the filling side of the IV Bag filling line, Equipment # (b) (4) while filling 1 mg/ml Midazolam in 0.9% Sodium Chloride 100 ml, Batch: (b) (4) Lot: (b) (4), Released: 07/28/2021, Expiration Date: 02/12/2022.

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Your investigation, MIR-2021-310, concluded that multiple equipment malfunctions including (b) (4) are the root cause of these overaction limit particle counts. You determined, without adequate justification, that there is no product impact as a result of these over-action in-process particle count events and you released each lot in full for distribution.

b. Your investigation, MIR-2021-421, was written for four events of over-action in-process particle counts (Action Limit: ≤ (b) (4) particles/ft³ over (b) (4) µm) on the IV Bag filling line, Equipment # (b) (4) during production of drug products as follows:

   i. On 07/27/2021, in-process environmental monitoring detected 102.0 particles/ft³ over (b) (4) µm on the filling side of the IV Bag filling line, Equipment # (b) (4) while filling 1 mg Fentanyl in 0.9% Sodium Chloride Injection 100 ml (10 mcg/ml) Batch: (b) (4) , Lot: (b) (4), Released: 08/30/2021, Expiration Date: 03/23/2022. Your investigation concluded that the (b) (4) . This implies that the filling system and designed flow of HEPA filtered air is incapable of excluding particles generated on the component side from the filling side near the filling needles. You determined, without adequate justification, that there is no product impact as a result of this over-action in-process particle count event and you released the lot in full for distribution.

   ii. On 08/02/2021, in-process environmental monitoring detected 108.0 particles/ft³ over (b) (4) µm on the filling side of the IV Bag filling line, Equipment # (b) (4) while filling 2.5 mg Fentanyl in 0.9% Sodium Chloride Injection 250 ml (10 mcg/ml) Batch: (b) (4) Lot: (b) (4), Released: 08/30/2021, Expiration Date: 03/30/2022. Your investigation concluded that (b) (4)

   You determined, without adequate justification, that there is no product impact as a

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result of this over-action in-process particle count event and you released the lot in full for distribution.

iii. On 08/04/2021, in-process environmental monitoring detected 162.0 particles/ft³ over (b) (4) µm on the filling side of the IV Bag filling line, Equipment # (b) (4) while filling 1 mg Fentanyl in 0.9% Sodium Chloride Injection 100 ml (10 mcg/ml) Batch: (b) (4) , Lot: (b) (4), Released: 09/08/2021, Expiration Date: 04/01/2022. There were no corrective actions reported in your investigation. You determined, without adequate justification, that there is no product impact as a result of this over-action in-process particle count event and you released the lot in full for distribution.

iv. On 08/11/2021, in-process environmental monitoring detected 103.0 particles/ft³ over (b) (4) µm on the filling side of the IV Bag filling line, Equipment # (b) (4) while filling 1 mg Fentanyl in 0.9% Sodium Chloride Injection 100 ml (10 mcg/ml) Batch: (b) (4) Lot: (b) (4). Your investigation concluded that particles were generated in the filler zone due to (b) (4) . Your investigation concluded, without adequate justification, that there is no product impact as a result of this over-action in-process particle count event and disposition of the subject lot is pending review.

c. Your investigation, MIR-2021-463, was written for two events of over-action in-process particle counts on the IV Bag filling line, Equipment # (b) (4) during production of drug products as follows:

i. On 08/20/2021, in-process environmental monitoring detected 894.0 particles/ft³ over (b) (4) µm, exceeding the Action Limit: ≤ (b) (4) particles/ft³ over (b) (4) µm, on the filling side of the IV Bag filling line, Equipment # (b) (4) while filling 1 mg/ml Midazolam in 0.9% Sodium Chloride 100 ml, Batch: (b) (4) , Lot: (b) (4).

ii. On 08/23/2021, in-process environmental monitoring detected 148.0 particles/ft³ over (b) (4) µm, exceeding the Action Limit: ≤ (b) (4) particles/ft³ over (b) (4) µm, on the filling side of the IV Bag filling line, Equipment # (b) (4) while filling 1 mg/ml

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Midazolam in 0.9% Sodium Chloride 100 ml, Batch: (b) (4) , Lot: (b) (4).

Your investigation, MIR-2021-463, determined that (b) (4) including a (b) (4) are the root cause of these overaction limit particle counts. Your investigation concluded, without adequate justification, that there is no product impact as a result of these over-action in-process particle count events and disposition of the subject lots is pending review.

**OBSERVATION 7**

Procedures for the cleaning and maintenance of equipment are deficient regarding the protection of clean equipment from contamination prior to use.

Specifically:

Equipment used on the IV bag filling line #(b) (4) including drug product component contact change parts and utensils required to be sterile is not adequately protected from contamination before use. Equipment and change parts used in production in the ISO 5 classified zone of the IV bag filling line, such as the utensil box, tweezers, scoop, and (b) (4) bowl is sterilized in (b) (4) (b) (4) #(b) (4). This (b) (4) is situated in an unclassified area adjacent to the process (b) (4) production area. Per SOP PRD213, "Sterilization of Bag Filler Components and Equipment in (b) (4) " the equipment is (b) (4) wrapped in "(b) (4) or equivalent" prior to sterilization in the (b) (4) and any rips in the outer foil layer may be repaired with (b) (4) tape. After the wrapped equipment is sterilized, it is removed from the (b) (4) and placed on a transfer cart, the cart is moved to the controlled unclassified "transition area," and the outer layer of foil is sprayed with sterile (b) (4)

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The SOP does not specify for how long the equipment may remain in the transition zone wrapped in foil prior to use.

**OBSERVATION 8**

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.

Specifically:

1. You have not validated (b) (4) in BFS machines BFS (b) (4) Equipment # (b) (4) and BFS (b) (4) , Equipment # (b) (4) More specifically you have not validated that time temperature conditions of the (b) (4) process are effective against endotoxin or spore challenges in the (b) (4) material that makes up the drug product primary container closure.

   BFS (b) (4) is used to produce drug products intended to be sterile including 20mg Phenylephrine HCl in 0.9% Sodium Chloride Injection, Batch: (b) (4) packaged as Lot: (b) (4), Released: 04/30/2021, Expiration Date: 01/30/2022.

   BFS (b) (4) is used to produce drug products intended to be sterile including Sodium Bicarbonate 150mEq/1000ml in 5% Dextrose Injection, Batch: (b) (4) , packaged as Lot: (b) (4), Released: 02/23/2021, Expiration Date: 12/28/2021.

2. Operators are permitted to participate in aseptic production on a given line prior to completing a successful aseptic simulation on that line. For example:

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a. Operator (b)(6) participated in the production of commercial sodium bicarbonate batches (b)(4) in June 2019 and (b)(4) in July 2019 on the IV bag filling line # (b)(4) One of (b)(6) roles is to spray the outer package of the sterile IV bags with sterile (b)(4) and place the package in the material (b)(4) adjacent to the bag filling station, as documented in step (b)(4) of batch (b)(4) The only aseptic simulation documented in (b)(6)'s training record was on the syringe line # (b)(4) on January 27, 2021. This occurred both after (b)(6) participated in commercial aseptic production on the IV bag filler in 2019 and on a different production line (syringe line # (b)(4) No documentation of (b)(6) participating in an aseptic simulation on the IV bag filling line # (b)(4) has been provided.

b. Operator (b)(6) participated in the production of commercial sodium bicarbonate batches (b)(4) and (b)(4) in March 2019 on the IV bag filling line # (b)(4) One of (b)(6) roles on this line is collecting (b)(4) bioburden samples, as documented in step (b)(4) of batch (b)(4) (b)(6) completed an aseptic simulation on this line in September 2019, after the batches were produced in March 2019. Thus, (b)(6) participated in aseptic production prior to participating in an aseptic simulation for that production line.

**OBSERVATION 9**

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically:

You permit personnel to enter packaging areas and conduct packaging operations in their street clothes and footwear. Your Change Control, CC No. CC-2020-043, approved on 04/09/2020, permitted temporary deviation from your procedure ADM102, Facility and Gowning, due to a shortage of supplies. During the inspection on 09/22/2021 we observed packaging and inspection personnel dressed

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in street clothes and personal footwear handling BFS IV bags containing 150 mEq Sodium Bicarbonate in 5% Dextrose Injection 1,000 mL (12.6mg/mL) BFS IV Bag, Batch # (b) (4) in controlled unclassified Packaging Room (b) (4) Personnel in street clothes, handled the drug product for visual inspection and insertion of the BFS IV bags into secondary packaging (pouches) before sealing.

**OBSERVATION 10**

The written stability program for drug products does not include meaningful test methods.

Specifically:

Your stability program SOP-VAL-0097 does not evaluate the photostability of light-sensitive drug products in the marketed packaging. Examples of such products are 2 mg epinephrine in 0.9% sodium chloride injection 250 mL (8 mcg/mL) and 1 mg fentanyl in 0.9% sodium chloride injection 100 mL (10 mcg/mL). Although in accordance with your protocols the stability samples remain within their marketed secondary packaging consisting of foil-lined pouches throughout the hold time, your firm lacks sufficient evidence through direct testing to show that the secondary packaging adequately protects drug products from light.

**OBSERVATION 11**

Employees are not given training in the particular operations they perform as part of their function.

Specifically:

1. Investigation MIR-2020-008 states that a root cause of the sterility failure for 150 mEq sodium bicarbonate in 5% dextrose batch (b) (4) /Lot (b) (4), manufactured (b) (4) , was a lack of

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training of an operator (b) (6) participating in the aseptic production of that batch. The batch was produced on IV Bag filling line #(b) (4) and the organism was identified as *Burkholderia multivorans*. MIR-2019-394 was opened to address (b) (6) production activities prior to training. It indicates that (b) (6) did not complete the prerequisite training module MOD00002 "General GMP" until 12/23/19, 10 days after (b) (6) participated in batch production. This practice conflicts with your SOP QAS 209 "Training Program," which states, "Employees, consultants, interns and contractors will be trained on procedures required to perform their job functions prior to performing the tasks described in the procedure."

2. Operator (b) (6) participated in the production of commercial sodium bicarbonate batches (b) (4) and (b) (4) on the IV bag filling line ((b) (4) in March 2019. (b) (6) training record shows that (b) (6) was "first trained" to operate the bag filling line in early March 2019 but was not considered "fully trained" until September 6, 2019, which is after batches (b) (4) and (b) (4) were produced. Training form TRN00114-ASSESS (Version A) defines "first training" as watching the activity, and "full training" as performing the activity independently and accurately. Thus, (b) (6) participated in aseptic production prior to being certified to perform production independently and accurately.

**OBSERVATION 12**

Complaint records are deficient in that they do not include the known reply to complainant.

Specifically:

Complainants do not always receive a final written response to their drug product complaint. For instance, you have received complaints for four adverse events since the last inspection and investigated these, but your records do not include a final written response to the complainant regarding investigation findings. Firm management confirmed that a written response was not issued. SOP QAS205 "Customer Complaints and Adverse Events" also does not require a written response to the complainant.

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Some complaint records do include e-mail correspondence between SterRx personnel and complainants, but without a formal final response. For example:

1. Product complaint PC-2019-011, concerning a hair found on the outside of a pouch of 20 mg phenylephrine in 0.9% sodium chloride (lot (b) (4), manufactured (b) (4) ), contains the following text in an e-mail from the supervising pharmacist to the complainant: "Our sterile phenylephrine IV product is filled and sealed within a sterile ISO5 (b) (4) system. The sealed bottle is then labeled and packaged in a clean room."
   This lot was produced on blow-fill-seal (BFS) machine (b) (4) in Filling Room (b) (4) The containers were capped in a separate ISO 7 area. The sealed containers were then labeled and packaged (pouched) in an unclassified room.

2. Complaint record PC-2020-135, regarding broken IV bags of 150 mEq sodium bicarbonate in 5% dextrose (Lot (b) (4), manufactured (b) (4) ) includes an e-mail from the supervising pharmacist to the complainant stating that your (b) (4) filling system "fills and seals the sterile container within an ISO5 chamber. This sealed and sterile final product is then inspected, labeled, and placed in the labeled foil pouch in an ISO7 room." This lot was produced on the IV bag filling line ((b) (4) in Filling Room (b) (4) and inspected, labeled, and packaged (pouched) in an unclassified room. The complainant replies to the supervising pharmacist, "This information confirms my understanding of your processes, which was that the package preparation and filling all take place in an ISO5 or better environment and the integrity of the drug was never compromised or in danger of being compromised."

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|---|---|---|---|

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 158-15 Liberty Avenue<br>Jamaica, NY 11433<br>(718) 340-7000 Ext:5301 Fax:(718)662-5661<br>ORAPHARM1_RESPONSES@fda.hhs.gov | 9/21/2021-11/4/2021*<br>FEI NUMBER<br>3010840309 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sarah J. McCoy, Director, Plant Operations

| FIRM NAME | STREET ADDRESS |
|---|---|
| SterRx, LLC | 141 Idaho Ave |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Plattsburgh, NY 12903-3987 | Outsourcing Facility 503B |

9/21/2021(Tue), 9/22/2021(Wed), 9/23/2021(Thu), 9/24/2021(Fri), 9/27/2021(Mon), 9/28/2021(Tue), 9/29/2021(Wed), 9/30/2021(Thu), 10/01/2021(Fri), 10/12/2021(Tue), 10/19/2021(Tue), 10/27/2021(Wed), 11/04/2021(Thu)

Lori M Newman
Investigator
Signed By: 2003217758
Date Signed: 11-04-2021 12:58:56
X

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Edmund F Mrak, Investigator<br>Lori M Newman, Investigator<br>X | 11/4/2021 |

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

# 11

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

**NON-REFUNDABLE $1,000.00 FEE**

Rev (04/19/2022)

**Where is the facility located?** ☐ Nevada ☒ Out-of-State

| Type of Application (check applicable box) | | Wholesaler Business Type (check applicable box) |
|---|---|---|
| ☐ New Wholesaler<br>☒ Ownership Change<br>☐ Name Change<br>☒ Location Change (in-state only) | * If making a change, provide current license number:<br>WH 02253 | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Is your facility a reverse distributor?** ☐ Yes ☒ No

### Section 1: General Information

Facility Name: STERRX, LLC

Physical Address: 133 CONNECTICUT ROAD

City: PLATTSBURGH State: NY Zip: 12903

Mailing Address (if different from physical address): 141 IDAHO AVE.

City: PLATTSBURGH State: NY Zip: 12903

Telephone: 518-324-7879 Website: WWW.STERRX.COM

Name of Designated Representative (DR): KAREN GREENE

Licensing Company Email: truenorthconsultingiowa@gmail.c DR Email: KAREN.GREENE@STERRX.COM

| Entities the Wholesaler will Serve | Products to be Handled or Wholesaled |
|---|---|
| ☐ Pharmacies | ☒ Legend Pharmaceuticals, Supplies or Devices |
| ☐ Practitioners | ☐ Controlled Substances |
| ☒ Hospitals | ☐ Hypodermic Devices |
| ☐ Wholesalers | ☐ Veterinary Legend Pharmaceuticals |
| ☐ Others: | ☐ Others: |

### Section 2: History of Company

| | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✓ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | ✓ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | ✓ | |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✓ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✓ |

**If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # 3 . Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| 01/13/2023 | pending | VA | Henrico | Richmond |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| 220191 | | Virginia Board of Pharmacy | | |
| **Reason/Charge** | | | | |
| Please see attached. | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| SterRx, LLC | | | N/A | |
| **Name of Business/Industry/Entity** | | | | |
| as aboe | | | | |

**Provide explanation below:**

Please see attached.

JCHS

Original Signature (electronic, copies or stamps not accepted)

13 March 2023

Date

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: Attached

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

**Section 4: Publicly Traded Corporation**

State of Incorporation: n/a

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: n/a

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

**Section 6: Partnership**

Partnership Name: SterRx, LLC

Mailing Address: 141 Idaho Avnenue

City: Plattsburgh State: NY Zip: 12903

Telephone: 1-518-324-7879 Email: jwebb@sagentpharma.com

Contact Person Name: Jerry Webb, EVP Operations

**Section 7: Sole Owner**

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | ✓ | |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | ✓ | |
| 1. Copy of FDA registration<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partner-ship | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** | | ✓ | | |
| • **List of all partners and their percent ownership.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

SterRx, LLC

Facility Name

Jerry C. Webb

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

13 March 2023

Date

| Board Use Only | Date Received: 3.20.23 | Amount: 1000.00 CC |
|---|---|---|

**William Wrisley**

**From:** edrls@fda.hhs.gov
**Sent:** Monday, December 07, 2015 11:20 AM
**To:** wwrisley@aseptpak.com
**Subject:** Labeler Code Request Approved

eDRLS - Electronic Drug Registration & Listing System

**Current Date: 07-DEC-15**
**Labeler DUNS: 049167014**
**Labeler Name: SterRx LLC**
**Labeler Code: 70324**

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. **To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.**

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) § 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).

**William Wrisley**

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**Sent:** Monday, December 07, 2015 11:20 AM
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Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).

SterRx® STERILE MANUFACTURER OF 503B COMPOUNDED DRUGS

SterRx, LLC
141 IDAHO AVENUE
PLATTSBURGH, NY 12903
844.319.7799

# FACILITY DESCRIPTION

## 133 CONNECTICUT ROAD, PLATTSBURGH, NY 12903

SterRx, LLC is an FDA-registered, 503B Outsourcing facility located at 141 Idaho Avenue, Plattsburgh, NY. SterRx manufactures and ships only their own finished, compounded drug products directly to their customers.

SterRx has secured a warehouse facility located at 133 Connecticut Road. The warehouse is 0.3 miles from SterRx's manufacturing building located at 141 Idaho Avenue. 133 Connecticut Road will function as a Shipping/Receiving warehouse for SterRx. In this facility, SterRx will ship finished SterRx products, receive and store API pharmaceutical ingredients and packaging components, as well as dispense bulk API ingredients.

The FDA identifies and registers the 133 Connecticut Road warehouse as part of SterRx's 141 Idaho Avenue manufacturing campus. The Connecticut Road facility will operate under the same FDA Establishment #, Federal Tax ID # and legal organization as SterRx's 141 Idaho Avenue facility. There will be no compounding activity, nor Controlled Substances, located at 133 Connecticut Road. At no point in time will there be a transfer of product ownership, or any wholesaling activities taking place. All drug products will remain under the ownership of SterRx, LLC.

The warehouse facility is a 60,000 sq. ft. pre-engineered insulated metal building with a new HVAC system, propane generator, parking lot for 77 spaces and storm water management system. The mezzanine floor will house office space, open workspace, conference room space, a kitchenette and washrooms. The main floor will be mainly comprised of warehouse space, as well as a reception, conference spaces and washrooms. There are 8 various-height dock doors located on the east side of the building.

The facility is environmentally controlled, employing a HVAC Direct Digital Control system, a boiler, chiller, two roof-top units, an air handling unit and two air rotation units. The HVAC system is designed to control the temperature thermostatically, at a temperature between 20 and 25 Celsius and a relative humidity below 40%. The facility has the capacity to seat 77 employees.

SterRx, LLC manufacturers sterile liquid pharmaceuticals under blow-fill-seal, aseptic technology in a cGMP-compliant environment.

There is one general use entrance on the west side of the building that is monitored and has card access. Two other doors on the west side are restricted use; one in the warehouse near the holding/sample room and one at the south end of the warehouse. These are both emergency exit only

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PLATTSBURGH, NY 12903
844.319.7799

doors that are constantly monitored/alarmed. There are two doors on the north side of the building; one goes to the sprinkler room and the other goes to the mechanical room. Neither door has access to the interior of the building beyond those two rooms, both are card access and monitored.

There are two doors on the east side of the building; one has access to the trucker area and the other is to access the electrical room. The door to the trucker area allows entry to a room and restroom area during normal business hours, entry to the rest of the facility is prevented by a card access door that is monitored. Outside of normal business hours, the trucker area door is locked and monitored. The electrical room only has access from the exterior by means of a card reader. The door is constantly monitored.

SterRx® STERILE MANUFACTURER OF 503B COMPOUNDED DRUGS

**SterRx, LLC**
141 IDAHO AVENUE
PLATTSBURGH, NY 12903
844.319.7799

March 2, 2023

To Whom it May Concern:

Subject: Change of Ownership: SterRx, LLC

Please be notified that a 100% change in stock ownership, at a grandparent level, will be in effect at the following facility as of February 28, 2023:

SterRx, LLC
141 Idaho Avenue, Plattsburgh, NY 12903

Owners to be removed: Nichi-Iko Pharmaceutical Co, Ltd.
Sagent Pharmaceuticals, Inc.

New Owner: Que Pharma Inc.
251 Little Falls Drive
Wilmington, DE 19808

Please see the enclosed pre- and post-closing organizational chart.
**SterRx, LLC's management team will remain the same:**

Jerry Webb, EVP Operations
Sagent Pharmaceuticals
1901 N. Roselle Rd., #450
Schaumburg, IL 60195
ph: 1-847-908-1600

Sarah McCoy, Director Plant Ops
SterRx, LLC
141 Idaho Ave
Plattsburgh, NY 12903
ph: 1-518-324-7879

Thomas Dominy, PIC
SterRx, LLC
141 Idaho Ave
Plattsburgh, NY 12903
ph: 1-518-324-7879

SterRx's day-to-day operations will remain uninterrupted, continuing 'business as usual', under the same:

Federal Tax Identification Number: 61-1718460
DUNS Number: 049167014
FDA Establishment Number: 30-10840309
DEA Registration Number: RS0547591

Should additional information regarding this Change of Ownership, at the grandparent level, or any other questions regarding SterRx, LLC, please do not hesitate to contact us.

Sincerely,

DocuSigned by:
Jerry Webb
C6182DB908E349F...

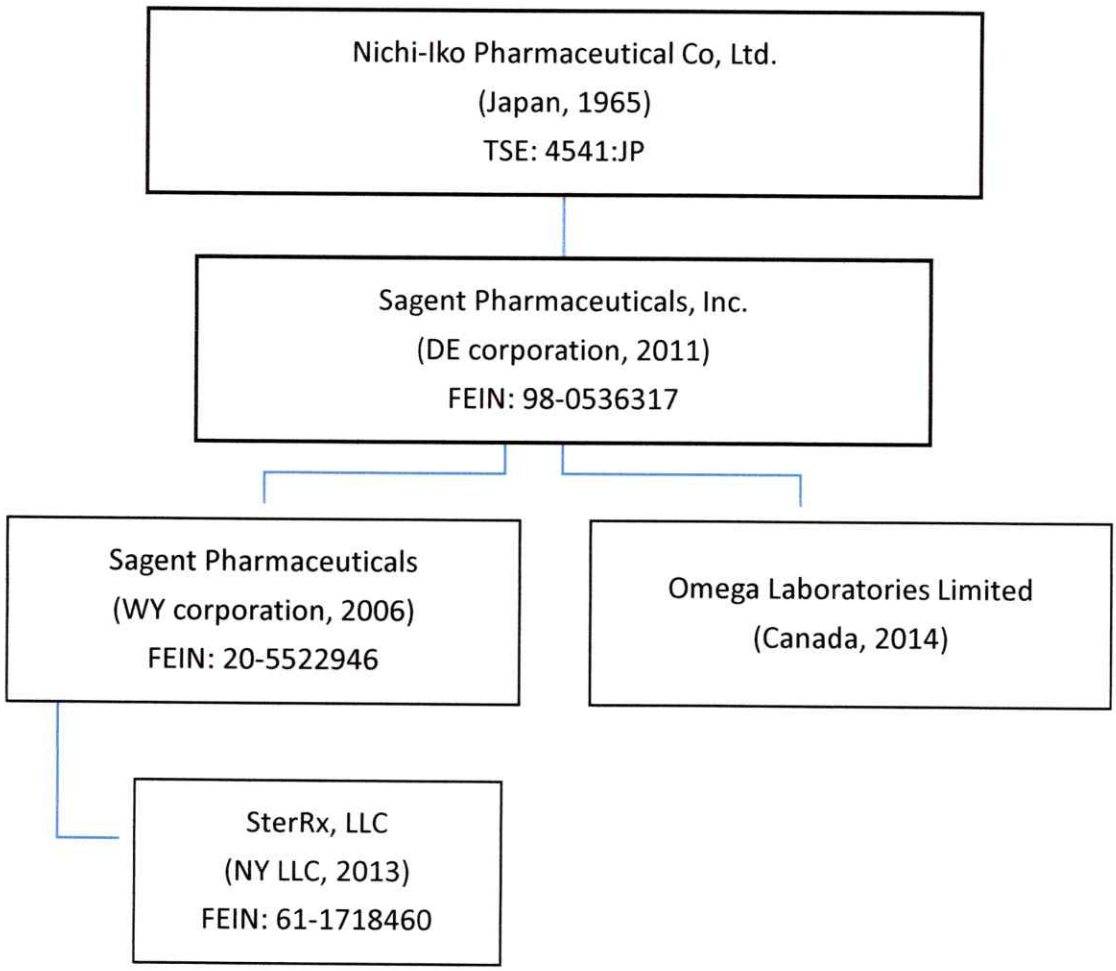
Jerry Webb
Sagent Pharmaceuticals

SterRx® STERILE MANUFACTURER OF 503B COMPOUNDED DRUGS

**SterRx, LLC**
141 IDAHO AVENUE
PLATTSBURGH, NY 12903
844.319.7799

# SterRx, LLC
# 2023 Change of Ownership
effective Closing Date: February 28, 2023

## PRE-CLOSING LEGAL STRUCTURE



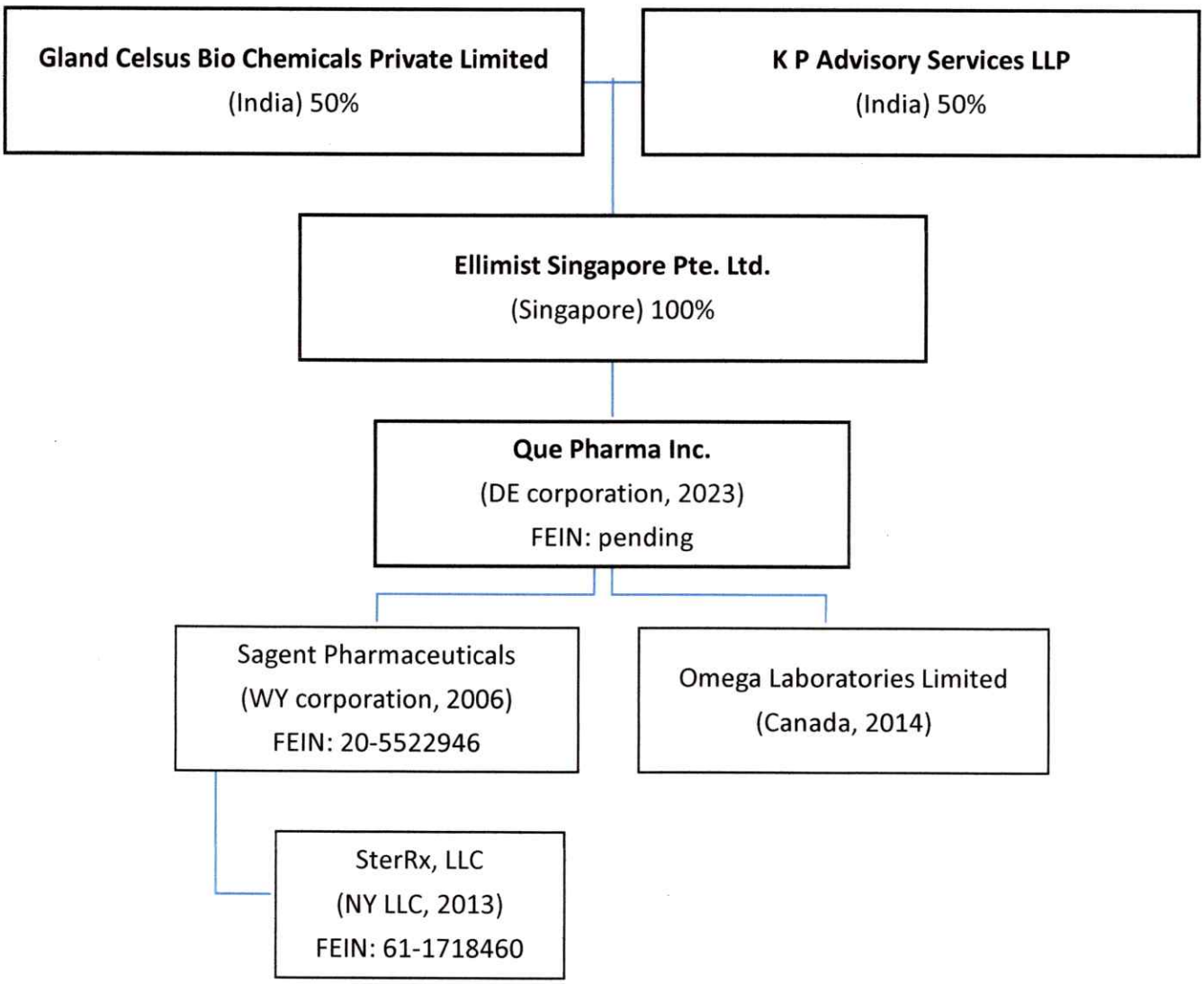

March 2, 2023

SterRx® STERILE MANUFACTURER OF 503B COMPOUNDED DRUGS

**SterRx, LLC**
141 IDAHO AVENUE
PLATTSBURGH, NY 12903
844.319.7799

# SterRx, LLC
# 2023 Change of Ownership
effective Closing Date: February 28, 2023

## POST-CLOSING LEGAL STRUCTURE




March 2, 2023

# SterRx, LLC - Capitalization Table – February 28, 2023

Organized in the State of New York

Federal Tax ID #: 61-171-8460

| | Pre-Closing | | | | Post-Closing | | | |
|---|---|---|---|---|---|---|---|---|
| **Unitholder** | **Common Units** | **Series A Preferred Units** | **Total** | **% FD** | **Common Units** | **Series A Preferred Units** | **Total** | **% FD** |
| Carl Martin | 0 | 882,353 | 882,353 | 5.6% | 0 | 882,353 | 882,353 | 5.6% |
| Kent Smeltz | 0 | 882,353 | 882,353 | 5.6% | 0 | 882,353 | 882,353 | 5.6% |
| Sagent Pharmaceuticals, Inc. | 6,058,250 | 3,921,569 | 9,979,819 | **72.1%** | 7,398,013 | 3,921,569 | 11,319,582 | **72.1%** |
| Timothy J. Miller | 100,000 | 0 | 100,000 | 0.6% | 100,000 | 0 | 100,000 | 0.6% |
| Justin L. Miller | 7,500 | 0 | 7,500 | 0.0% | 7,500 | 0 | 7,500 | 0.0% |
| Charles M. Kaulfuss itf Sandra Hawkins | 25,000 | 0 | 25,000 | 0.1% | 25,000 | 0 | 25,000 | 0.1% |
| Sandra Hawkins itf Charles M. Kaulfuss | 694,375 | 0 | 694,375 | 4.4% | 694,375 | 0 | 694,375 | 4.4% |
| Denis G. LaVigne & Dawn LaVigne | 170,700 | 0 | 170,700 | 1.1% | 170,700 | 0 | 170,700 | 1.1% |
| James McKee III | 475,000 | 0 | 475,000 | 3.0% | 475,000 | 0 | 475,000 | 3.0% |
| Next Generation Trust Services fbo Mary M. McKee | 475,000 | 0 | 475,000 | 3.0% | 475,000 | 0 | 475,000 | 3.0% |
| Jeff LaBombard | 500,000 | 0 | 500,000 | 3.2% | 500,000 | 0 | 500,000 | 3.2% |
| Winslow Moore and Vera Delorme | 154,412 | 0 | 154,412 | 1.0% | 154,411 | 0 | 154,412 | 1.0% |
| **TOTAL** | **10,000,000** | **5,686,275** | **15,686,275** | | **10,000,000** | **5,686,275** | **15,686,275** | |

*Note: percentages do not add to precisely 100.0% due to rounding

SterRx, LLC is 72.1% owned by Sagent Pharmaceuticals.
Sagent Pharmaceuticals is wholly owned by **Que Pharma, Inc.**

SterRx® STERILE MANUFACTURER OF 503B COMPOUNDED DRUGS

SterRx, LLC
141 IDAHO AVENUE
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# STERRX, LLC
# TOP FOUR SUPPLIERS

**Medisca**
661 NY-3
Plattsburgh, NY 12901

**Willow Birch**
433 Old Taylor Road
Taylor, MS 38673

**Spectrum Rx**
769 Jersey Avenue
New Brunswick, NJ 08901

**Fagron, Inc.**
2499 Pilot Knob Road Suite #200
St. Paul, MN 55120

# NABP ACCREDITED
## DRUG DISTRIBUTOR

SterRx LLC

located at

141 Idaho Ave, Plattsburgh, NY 12903-3987

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

**Lemrey "Al" Carter,** PharmD, MS, RPh
*Executive Director/Secretary*

6/10/2021 - 6/9/2024
Period of Accreditation

2988

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**SterRx, LLC**
141 IDAHO AVENUE
PLATTSBURGH, NY 12903
844.319.7799

# PROOF OF REGISTRATION with US FOOD AND DRUG ADMINISTRATION

1/15/23, 11:47 AM Registered Outsourcing Facilities | FDA

## Registered Outsourcing Facilities

**Facilities Registered As Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act)**

Updated as of 1/3/2023

- Information Concerning Outsourcing Facility Registration (/drugs/compounding/questions-and-answers-outsourcing-facility-registration)
- Outsourcing Facility Product Reporting Information (/drugs/compounding/information-outsourcing-facilities#reporting)

This table lists the outsourcing facilities that have submitted registration information that has been determined to be complete by the data lock date for the latest weekly update of the table.

| Facility Name | Contact Name and Phone Number | Initial Date of Registration as an Outsourcing Facility[1] | Date of Most Recent Registration as an Outsourcing Facility[1] | End Date of Last FDA Inspection Related to Compounding[2] | Was a Form FDA-483 issued?[3] | Other Action, if Any, Based on Last Inspection[4,5] |
|---|---|---|---|---|---|---|
| SterRx LLC, Plattsburgh, NY | Thomas J. Dominy 518-324-7879 Ext=1249 | 5/29/2015 | 10/31/2022 | 11/4/2021 | Yes (/media/156608/download) | Open[7] |

https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities

**FDA Facility Establishment #:** 3010840309
DUNS #: 049167014
Federal Tax ID #: 61-1718460

NAICS Code: 325412Pharmaceutical Preparation Manufacturing
SIC Code: 2834 Pharmaceutical Preparations

Sanitized Laberer 4/12/23

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| RS0547591 | 02-29-2024 | $3699 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,3,3N, 4,L1 | MANUFACTURER | 02-28-2023 |

STERRX LLC
141 IDAHO AVE
PLATTSBURGH, NY 129033987

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

**THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.**

**CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE**
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

| DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID |
|---|---|---|
| RS0547591 | 02-29-2024 | $3699 |

| SCHEDULES | BUSINESS ACTIVITY | ISSUE DATE |
|---|---|---|
| 2,3,3N, 4,L1 | MANUFACTURER | 02-28-2023 |

STERRX LLC
141 IDAHO AVE
PLATTSBURGH, NY 129033987

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

# THE UNIVERSITY OF THE STATE OF NEW YORK
# EDUCATION DEPARTMENT

# NEW YORK STATE BOARD OF PHARMACY

2022-25

NAME OF SUPERVISOR
THOMAS DOMINY

THIS IS TO CERTIFY

STERRX, LLC
141 IDAHO AVENUE
PLATTSBURGH, NY 12903

is duly recorded as a

## REGISTERED OUTSOURCING FACILITY

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE FIRST DAY OF MARCH, 2022.
THIS CERTIFICATE EXPIRES ON THE TWENTY-EIGHTH DAY OF FEBRUARY, 2025.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER
034102

EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

2991

# NEW YORK STATE DEPARTMENT OF HEALTH
## CONTROLLED SUBSTANCE LICENSE

STERRX LLC
141 IDAHO AVENUE
PLATTSBURGH NY 12903

CLASS 1
MANUFACTURER
SCHEDULE:
II III IV V

HAS GIVEN SATISFACTORY EVIDENCE THAT ALL QUALIFICATIONS AS REQUIRED BY ARTICLE 33 OF THE PUBLIC HEALTH LAW AND PART 80 OF THE ADMINISTRATIVE RULES AND REGULATIONS HAVE BEEN MET AND IS HEREBY GRANTED A LICENSE TO ENGAGE IN CONTROLLED SUBSTANCE ACTIVITY IN THE STATE OF NEW YORK IN THE CLASSIFICATION STATED ABOVE.

LICENSE #: 0100223
EFFECTIVE: MAY 22, 2022
EXPIRES: MAY 21, 2024

Mary T. Bassett

MARY T. BASSETT, M.D., M.P.H
COMMISSIONER OF HEALTH

TO BE PERMANENTLY DISPLAYED AT THE LICENSED SITE

**STATE OF NEW YORK**

**DEPARTMENT OF STATE**

**Certificate of Status**

I, ROBERT J. RODRIGUEZ, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

| | |
|---|---|
| **Entity Name:** | STERRX, LLC |
| **DOS ID Number:** | 4445915 |
| **Entity Type:** | DOMESTIC LIMITED LIABILITY COMPANY |
| **Entity Status:** | EXISTING |
| **Date of Initial Filing with DOS:** | 08/15/2013 |
| **Statement Status:** | CURRENT |
| **Statement Due Date:** | 08/31/2021 |

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on June 23, 2022 at 01:43 P.M.

ROBERT J. RODRIGUEZ, Secretary of State

Brendan C. Hughes

By Brendan C. Hughes
Executive Deputy Secretary of State

Authentication Number: 100001768273 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

# NABP ACCREDITED
## DRUG DISTRIBUTOR

SterRx LLC

located at

141 Idaho Ave, Plattsburgh, NY 12903-3987

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

**Lemrey "Al" Carter,** PharmD, MS, RPh
*Executive Director/Secretary*

6/10/2021 - 6/9/2024
Period of Accreditation

2994

| Firm Name | FDA Establishment Identifier | DUNS | Business Operations | Address | Expiration Date |
|---|---|---|---|---|---|
| SterRx LLC | 3010840309 | 049167014 | MANUFACTURE; REPACK; | 141 Idaho Avenue, Plattsburgh, New York (NY) 12903, United States (USA) | 12/31/2020 |

https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities

**Facilities Registered As Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act)**

| Facility Name | Contact Name and Phone Number | Initial Date of Registration as an Outsourcing Facility[1] | Date of Most Recent Registration as an Outsourcing Facility[1] | End Date of Last FDA Inspection Related to Compounding[2] | Was a Form FDA-483 issued?[3] | Other Action, if Any, Based on Last Inspection[4,5] | Intends to Compounds Sterile Drugs From Bulk Drug Substances[6] |
|---|---|---|---|---|---|---|---|
| Plattsburgh, NY | Sue Martin 518-324-7879 | 5/29/2015 | 12/05/2019 | 6/7/2019 | No | Open[7] | Yes |

http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm378645.htm

SterRx, LLC, 141 Idaho Avenue, Plattsburgh, NY 12903-3987
Office Phone: 518-324-7879 Toll free: 844-319-7799
DUNS: 049167014 (Used in lieu of FEI No {Facility Establishment Identifier})
FEIN: 61-1718460 (State and Federal)
Registration No.: 034102

NAICS Code: 325412Pharmaceutical Preparation Manufacturing
SIC Code: 2834 Pharmaceutical Preparations

# Employee Roster

As of Date: 03/09/2023

| COMPANY CODE | NAME | JOB TITLE |
|---|---|---|
| Company Code: MQZ | | 54 Employees in MQZ |
| MQZ | Allen, John C | 1040-Technical Service Specialist |
| MQZ | Ashline, Jacob | 1016-Materials Management Specialist |
| MQZ | Ashline, Kelly Lisa | 1067-Generalist, Human Resources |
| MQZ | Babbie, Nolan A | 1017-Materials Management Supervisor |
| MQZ | Bahner-Guhin, Sean E | 1016-Materials Management Specialist |
| MQZ | Banker-Godfrey, Rebecca Ann | 1003-HR Manager |
| MQZ | Barone, Jasmine Noelle | 1009-Compounding Pharmacist |
| MQZ | Birkett-Laramie, George P | 1016-Materials Management Specialist |
| MQZ | Bleau, Scott J | 1042-QA Specialist |
| MQZ | Bulluck, Austin Quinn | 1075-Senior Technical Support Specialist, IT |
| MQZ | Cameron, Joshua P | 1032-Production Manager |
| MQZ | Cotto, Rene | 1040-Technical Service Specialist |
| MQZ | Dominy, Thomas | 1071-Sr. Pharmacy Manager, DC & SP |
| MQZ | Dostie, Robert Dale | 1011-Process Engineer |
| MQZ | Drollette, Susan Elizabeth | 1009-Compounding Pharmacist |
| MQZ | Duprey, Mary | 1065-Manager, Technical Services |
| MQZ | Farrell, Nancy L | 1042-QA Specialist |
| MQZ | Fracalossi, Daniel H | 1040-Technical Service Specialist |
| MQZ | Greene, Karen A | 1072-Associate Director, Materials Management |
| MQZ | Hanley, Kyle J | 1073-Associate Dir, Engineering and Maintenance |
| MQZ | Harrington, Napoleon | 1048-Associate Director, Production |
| MQZ | Hemingway, Tara L | 1078-Sr. Manager, QA/QC Microbiology |
| MQZ | Hewitt, Philip R | 1017-Materials Management Supervisor |
| MQZ | Hubbard II, Charles Franklin | 1005-Site Controller |
| MQZ | Jubert, Darlene A | 1031-Production Supervisor |
| MQZ | Kellogg, Troy I | 1043-Stability Specialist |
| MQZ | King, Trever | 1011-Process Engineer |
| MQZ | Kirk, Matthew D | 1051-Sr. Manager, Environmental Health and Safety |
| MQZ | Lahue, Daniel Rufus | 1031-Production Supervisor |
| MQZ | Legacy, Eric Robert | 1040-Technical Service Specialist |
| MQZ | Levasseur, William D | 1016-Materials Management Specialist |
| MQZ | McCasland, Craig A | 1032-Production Manager |
| MQZ | McCoy, Sarah J | 1006-Director, Plant Operations |
| MQZ | McGovern, Linda M | 1059-Sr. Manager, Production Planner |

# Employee Roster

As of Date: 03/09/2023

| COMPANY CODE | NAME | JOB TITLE |
|---|---|---|
| MQZ | Melis, Adrianne L | 1042-QA Specialist |
| MQZ | Parent, Frederick J | 1030-Production Process Specialist |
| MQZ | Parker, Brian G | 1018-Buyer |
| MQZ | Pierce, Kyle Thomas | 1031-Production Supervisor |
| MQZ | Pierce, Rachel L | 1076-Supervisor, QC Microbiology |
| MQZ | Pilcher, Anthony S | 1044-Director, Research and Development |
| MQZ | Rabideau, Jeffrey Donald | 1069-Senior Supervisor, Maintenance |
| MQZ | Ressing, Rosanna C | 1009-Compounding Pharmacist |
| MQZ | Robert, Gerald A | 1016-Materials Management Specialist |
| MQZ | Roberts, Dennis F | 1031-Production Supervisor |
| MQZ | Roth, Tracy M | 1077-Director, QA & QC Microbiology |
| MQZ | Seguin, Jason J | 1016-Materials Management Specialist |
| MQZ | Sexton, Kitiara K | 1016-Materials Management Specialist |
| MQZ | Stephen, Shari Allx | 1040-Technical Service Specialist |
| MQZ | Stewart, Beth E | 1047-Maintenance Coordinator |
| MQZ | Tunnell, Gary | 1031-Production Supervisor |
| MQZ | Tuper, Adam | 1049-Sr. Manager, QC Chemistry |
| MQZ | Voyer, Brandy L | 1042-QA Specialist |
| MQZ | Wild, Mandi Waneta | 1062-Director, Human Resources |
| MQZ | Zaremba-Woodward, Scot P | 1030-Production Process Specialist |
| Company Code: NGG | | 113 Employees in NGG |
| NGG | Ackey, Marc | 1026-Operator |
| NGG | Babbie, Ryan Paul | 1045-Stock Clerk |
| NGG | Baillargeon, David T | 1027-Set up Operator |
| NGG | Baker, Michelle L | 1036-Packaging Lead |
| NGG | Barriere, Sydney Paige | 1024-QC Microbiology Analyst |
| NGG | Barry, Jason Michael | 1026-Operator |
| NGG | Bartlett, Darlene | 1035-Packaging Assistant |
| NGG | Bell, Haley | 1035-Packaging Assistant |
| NGG | Bernier, Alexandre | 1042-QA Specialist |
| NGG | Bisonette, Brenda | 1035-Packaging Assistant |
| NGG | Blake, Payton V | 1036-Packaging Lead |
| NGG | Blake, Rashaad | 1027-Set up Operator |
| NGG | Blanchard, Matthew David | 1024-QC Microbiology Analyst |
| NGG | Bouzidane, Jennifer C | 1036-Packaging Lead |



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# Employee Roster

As of Date: 03/09/2023

| COMPANY CODE | NAME | JOB TITLE |
|---|---|---|
| NGG | Brown, David R | 1064-Technical Services Specialist III |
| NGG | Burdick, Cathy A | 1034-Record Reviewer/Trainer |
| NGG | Burdo, Jonathan M | 1026-Operator |
| NGG | Buskey, Cody A | 1013-Maintenance Technician |
| NGG | Buskey, Rickey A | 1027-Set up Operator |
| NGG | Carter, Carlton C | 1022-Chemistry Analyst |
| NGG | Cereske, Raymond A | 1026-Operator |
| NGG | Cipriano, Adam J | 1013-Maintenance Technician |
| NGG | Clinebell, Betty M | 1036-Packaging Lead |
| NGG | Collins, Justin | 1012-Calibration Technician |
| NGG | Cooley, Chelsea Ellen | 1045-Stock Clerk |
| NGG | Covey, Christopher Ward | 1016-Materials Management Specialist |
| NGG | DeLutis, Eric Christopher | 1024-QC Microbiology Analyst |
| NGG | Doran, Cameron Richard | 1024-QC Microbiology Analyst |
| NGG | Dougherty, Merwin J | 1027-Set up Operator |
| NGG | Doyle-Ashline, Jennifer Marie | 1035-Packaging Assistant |
| NGG | Duffield, Connor Nathaniel | 1028-Process Helper |
| NGG | Dumar, Christopher Edward | 1035-Packaging Assistant |
| NGG | Dupre, Annabelle Elizabeth | 1022-Chemistry Analyst |
| NGG | Eilers, Sarah L | 1068-Senior Accounting Clerk |
| NGG | Estes, Brenden Todd | 1035-Packaging Assistant |
| NGG | Fairclough, Kerryann A | 1035-Packaging Assistant |
| NGG | Favro, David Allen | 1035-Packaging Assistant |
| NGG | Fifield, Mollie A | 1035-Packaging Assistant |
| NGG | Fisher, Nicholas E | 1035-Packaging Assistant |
| NGG | Fisher, Sarah Joan | 1035-Packaging Assistant |
| NGG | Foster, Mallory L | 1000-Administrative Assistant |
| NGG | Gamache, Toby Lee | 1045-Stock Clerk |
| NGG | Gapp, Marguerite Alice | 1035-Packaging Assistant |
| NGG | Garrant, Jennifer Amy | 1042-QA Specialist |
| NGG | Gaudette, Jeffery L | 1034-Record Reviewer/Trainer |
| NGG | Hamilton, Charles E | 1022-Chemistry Analyst |
| NGG | Henry, Kevin P | 1035-Packaging Assistant |
| NGG | Hubbell, Audrey A | 1037-Chemistry/ R&D Analyst |
| NGG | Imondi, Ryan | 1035-Packaging Assistant |

# Employee Roster

As of Date: 03/09/2023

| COMPANY CODE | NAME | JOB TITLE |
|---|---|---|
| NGG | Irwin, Nathan G | 1027-Set up Operator |
| NGG | Kemp, Tristan | 1037-Chemistry/ R&D Analyst |
| NGG | Kourofsky, Kyle J | 1026-Operator |
| NGG | LaMoy, Cody D | 1043-Stability Specialist |
| NGG | Labarge, Steven L | 1029-Production Lead |
| NGG | Lafountain, Francis G | 1029-Production Lead |
| NGG | Lafountain, Gregory L | 1013-Maintenance Technician |
| NGG | Laframboise, Ulrick Simon | 1035-Packaging Assistant |
| NGG | Laperle, Philippe T | 1038-Chemistry/ R&D Technician |
| NGG | Larock, Allison B | 1024-QC Microbiology Analyst |
| NGG | Larock, Gabriel W | 1026-Operator |
| NGG | Levasseur, Joshua R | 1029-Production Lead |
| NGG | Lewis, Christopher L | 1042-QA Specialist |
| NGG | Lubic, Mark Allan | 1013-Maintenance Technician |
| NGG | MacDougal, Katelynn E | 1035-Packaging Assistant |
| NGG | MacDougal, Louann | 1045-Stock Clerk |
| NGG | Maes, Julien G | 1022-Chemistry Analyst |
| NGG | Martin, Cody R | 1013-Maintenance Technician |
| NGG | Martin, Kali L | 1035-Packaging Assistant |
| NGG | Mattel-Burr, Martin W | 1026-Operator |
| NGG | McCadam, Ann Victoria | 1026-Operator |
| NGG | McEneany, Eric Lee | 1024-QC Microbiology Analyst |
| NGG | Mercaldi, Shawn A | 1013-Maintenance Technician |
| NGG | Merker, Belinda Rose | 1024-QC Microbiology Analyst |
| NGG | Millett, Matthew Mark | 1024-QC Microbiology Analyst |
| NGG | Mosher, Michelle Yvette | 1035-Packaging Assistant |
| NGG | Murphy, Thor M | 1027-Set up Operator |
| NGG | Ngoma, Marlon Christ | 1035-Packaging Assistant |
| NGG | Ondras, Tanya L | 1023-Custodian |
| NGG | Oneal, Andree L | 1035-Packaging Assistant |
| NGG | Patitucci, Jesse Thomas | 1016-Materials Management Specialist |
| NGG | Pelno, Lauren Michelle | 1035-Packaging Assistant |
| NGG | Perry, Pauline P | 1035-Packaging Assistant |
| NGG | Pummell, Ian R | 1079-Lead, QC Microbiology Analyst |
| NGG | Rancour, Samantha L | 1035-Packaging Assistant |

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# Employee Roster

As of Date: 03/09/2023

| COMPANY CODE | NAME | JOB TITLE |
|---|---|---|
| NGG | Riley, Melissa Marie | 1035-Packaging Assistant |
| NGG | Rivers, Matthew W | 1013-Maintenance Technician |
| NGG | Roberts, Haley Elizabeth | 1035-Packaging Assistant |
| NGG | Rock, Kattie Gale | 1035-Packaging Assistant |
| NGG | Rock, Ryan T | 1038-Chemistry/ R&D Technician |
| NGG | Rollings, Victor Frank | 1036-Packaging Lead |
| NGG | Roushia, Amanda Leigh | 1036-Packaging Lead |
| NGG | Ruger, Shawn Terry | 1035-Packaging Assistant |
| NGG | Sand, Diane Sarah | 1022-Chemistry Analyst |
| NGG | Seguin, Kristina M | 1045-Stock Clerk |
| NGG | Shambo, April L | 1035-Packaging Assistant |
| NGG | Shand, Napoleon St Mark Trelawny | 1024-QC Microbiology Analyst |
| NGG | Smith, Lacy | 1023-Custodian |
| NGG | Snider, Stacey L | 1035-Packaging Assistant |
| NGG | Stemper, Eric P | 1035-Packaging Assistant |
| NGG | Stowell, Celine Morgan | 1035-Packaging Assistant |
| NGG | Suddard, Terri S | 1045-Stock Clerk |
| NGG | Tetreault, Mark F | 1020-CDL Driver |
| NGG | Trim, Aaron | 1045-Stock Clerk |
| NGG | Tubo, Bruce L | 1079-Lead, QC Microbiology Analyst |
| NGG | Valentine, Robert H | 1045-Stock Clerk |
| NGG | Vanvalkenburg, Nora E | 1036-Packaging Lead |
| NGG | Vassar, Brady Alexander | 1024-QC Microbiology Analyst |
| NGG | Waterous, Julia Marie | 1024-QC Microbiology Analyst |
| NGG | Watson, Olivia Shaneika | 1035-Packaging Assistant |
| NGG | Wells, Tammy | 1035-Packaging Assistant |
| NGG | Worley, Madison Alexis | 1024-QC Microbiology Analyst |
| NGG | Yelle, Lisa A | 1036-Packaging Lead |
| NGG | Zachary, Kristy L | 1035-Packaging Assistant |

Count of Employees: 167

**Report Runtime Settings** The following settings were used to create this report

## Employees Included

Employee List
**All Active Employees**

Company Codes
**MQZ-STERRX LLC, NGG-STERRX LLC**

Home Departments
**All Home Departments**

Locations
**All Locations**

Business Units
**All Business Units**

Archived employees are NOT included

Employees with payroll history are NOT included

## Fields Included

Company Code, Name, Job Title

## Sort Order

Company Code, Name

## Group By

Company Code

## Display Options

Tax ID is Fully Masked

Currency Conversion No

Report Information displayed as of 03/09/2023

## Note

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/13/2022)

### Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler SterRx, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable) as above

Physical Address 141 Idaho Avenue

City Plattsburgh State NY Zip 12903

Mailing Address (if different from physical address) as above

City _____ State _____ Zip _____

Telephone 1-518-324-7879 Website www.sterrx.com

Licensing Company Email truenorthconsultingiowa@gmail.com

### Section 2: Personal Information

First Jerry Middle Charles Last Webb

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]N. Roselle Road, suite [redacted]

City Schaumburg State IL Zip 60195

Telephone [redacted] Email jwebb@sagentpharma.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | ✓ | |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Attached. | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 2006 - present | [redacted]Sycamore Springs Place | Mountain Home | AR | 72653 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| | | | |
|---|---|---|---|
| Business Name<br>Attached. | | | From - To (MM/YY – MM/YY) |
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| | | | |
|---|---|---|---|
| Business Name | | | From - To (MM/YY – MM/YY) |
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| | | | |
|---|---|---|---|
| Business Name | | | From - To (MM/YY – MM/YY) |
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| | | | |
|---|---|---|---|
| Business Name | | | From - To (MM/YY – MM/YY) |
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| | | | |
|---|---|---|---|
| Business Name | | | From - To (MM/YY – MM/YY) |
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✓ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✓ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | ✓ | |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # 6. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| 01/13/2023 | pending | VA | Henrico | Richmond |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| 220191 | | Virginia Board of Pharmacy | | |
| **Reason/Charge** | | | | |
| Please see attached. | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | **Lawsuit/Arbitration/Bankruptcy** | | |
| Virginia Board of Pharmacy/SterRx, LLC | | | | |
| **Name of Business/Industry/Entity** | | | | |
| SterRx, LLC | | | | |

**Provide explanation below:**

Please see attached.

JCW

Original Signature (electronic, copies or stamps not accepted)

13 March 2023

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Jerry Webb

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

13 March 2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of ILLINOIS, ss. County of DUPAGE

I, Amy L Sorapuru, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

13 March 2023

**Date**

Subscribed and Sworn to before me this 13 day of MARCH 2023.

Amy L Sorapuru

**Notary Public Signature**

AMY L. SORAPURU
OFFICIAL SEAL
Notary Public, State of Illinois
My Commission Expires
August 26, 2025

**(Seal)**

I, Thomas Dominy, **certify that as the designated representative for**

SterRx, LLC,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. DS I am at least 21 years of age;
3. DS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. DS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. DS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. DS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. DS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Thomas Dominy

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

13 Mar 2023

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Thomas Dominy

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

13 Mar 2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of New York, ss. County of Clinton

I, Thomas Dominy, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

14 Mar 2023

**Date**

Subscribed and Sworn to before me this 14th day of March 2023

**Notary Public Signature**

HEATHER J. RANCOUR
Notary Public, State of New York
No. 01RA6215083
Qualified in Clinton County
Commission Expires December 21, 2025

**(Seal)**

**Jerry C. Webb**

[redacted]Sycamore Springs Place Mountain Home, AR

[redacted]

**Professional Experience**

September 2019 to present

Executive Vice President, Operations

Sagent Pharmaceuticals LLC

Schaumburg, IL

*Executive responsibilites for Operations, which includes Manufacturing, Quality, Regulatory Affairs, Product Development, and full P&L for the Omega Laboratories Generic Drug business in Canada. Sagent is a major Generic Drug provider For the US market, ($350 million in sales) acquiring finished sterile injectables from 24 different contract manufacturing organizations across the globe.*

July 2014 to September 2019

Senior Vice President of Quality

NantWorks, LLC Culver City, CA

*Executive responsibilities for Quality for NantPharma, NantBioScience, NantCell, and NantOmics. These businesses covered a spectrum of biotech products and services for leading edge treatment of cancer. There was a network of product development locations, manufacturing facilities, and a full service clinical operations group. There was also a portfolio of key suppliers, providing contract capabilities to augment the effort.*

August 2012 to July 2014

Chief Scientific Officer

Nephron Pharmaceuticals LLC

Orlando, FL

*Executive responsibilities for the scientific community within a privately held company. Areas of responsibility include Quality Assurance, Quality Control, Research and Development, Formulation, and Regulatory Affairs. Company manufactures sterile inhalable solutions.*

March 2008 to August 2012

Vice President and General Manager

Active BioMaterials LLC Los Angeles, CA

*Executive responsibilities for a $70 million API business. Instituted an international network of raw material suppliers and logistics (11 collection operations in the US, Canada, and the EU) to support two GMP processing plants, one for Starting Material and one for API. Negotiated major contract for sales of crude materials, and established partnerships with suppliers to insure long term supply of traceable mucosa. Responsible for Manufacturing, Quality, Supply Chain, R & D and the Commercial Operations.*

June 2005 to March 2008

Vice President of Quality

Boston Scientific Corporation Marlborough, MA

*Executive responsibilities for Quality in a Group of four Divisions with revenues of $1.8 billion. There was a network of 6 manufacturing plans (2 international) and Design Assurance organizations for the 4 divisions. Core business comprised of minimally invasive Medical Devices (FDA Class II and III).*

January 2004 to June 2005

Sr Vice President of Technical Affairs

Cardinal Health Integrated Provider Services

McGaw Park, IL

*Executive responsibilities for Quality and Environmental, Health and Safety in a Segment of with revenues of $12 billion. There was a network of 20 manufacturing plants (12 international), 70 distribution centers (25 international) and 80 pharmacies. Core businesses were Medical Devices (FDA Class I and II), Generic Drugs and Nuclear Pharmacies.*

October 2001 to January 2004

Vice President of Quality

Cardinal Health Biotechnology and Sterile Life Sciences

Woodstock, IL

*Executive responsibilities for Quality in a Division with revenues of $300 million. There was a network of 5 manufacturing plants. Core business was Contract Manufacturing for Aseptically Processed Sterile Drugs.*

September 1996 to October 2001

Vice President, Quality Management

Allegiance Healthcare

McGaw Park, IL

*Executive responsibilities for the Allegiance Quality System, supporting Manufacturing, Distribution and Equipment Servicing to meet FDA and EU requirements.*

November 1994 to September 1996

Plant Manager

Baxter de Chile, Ltda

Santiago, Chile

*Management responsibilities for Manufacturing, Distribution, Equipment Servicing and Quality. Core businesses were Large Volume Parenterals, Dialysis Solutions, Dialysis Equipment Servicing, Importation and Distribution.*

January 1994 to November 1994

Plant Manager

Baxter Anesthesia Division

North Reading, MA

*Management responsibilities for Manufacturing, Design Assurance, Equipment Servicing and Quality. Core business was Infusion Pumps.*

August 1991 to January 1994

Plant Manager

Baxter Singapore Pte Ltd

Singapore

*Management responsibilities for Manufacturing and Engineering. Core business was Infusion Pumps.*

February 1989 to August 1991

Director of Quality and Regulatory

Baxter Auto Syringe Division

Hooksett, NH

*Management responsibilities for Quality and Regulatory Affairs, Service and P & L responsibility for an OEM-based disposable products business. Core Business was Infusion Pumps.*

October 1984 to February 1989

Quality Operations Manager

Baxter Drug Delivery Plant

Round Lake, IL

*Management responsibilities for Quality support of an aseptic processing operation for cephalosporins and penicillins which were distributed in frozen minibags.*

February 1981 to October 1984

Various positions in Quality

Travenol Laboratories Inc

Mountain Home Plant

Mountain Home, AR

*Worked as a Formulation Chemist for anticoagulant solutions, as a Quality Supervisor for operations such as packing lines for blood collection units, donor needle assembly, plastic extrusion, RF sealing to make containers and molding, and as Staff Assistant to Quality Manager.*

**Educational Background**

B.S. Biology University of Arkansas Little Rock, AR

Graduate Studies in Chemistry Virginia Commonwealth University Richmond, VA

# COMMONWEALTH of VIRGINIA

Arne W. Owens
Director

*Department of Health Professions*
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

www.dhp.virginia.gov
PHONE (804) 367- 4400

**Board of Pharmacy**
**804/367-4456**
**804-527-4472 (fax)**

January 13, 2023

Certified Article Number
9414 7266 9904 2198 8143 96
SENDER'S RECORD
**Request return receipt**

Thomas Dominy, Pharmacist-in-Charge
SterRX, LLC
141 Idaho Avenue
Plattsburgh, NY 12903

**RE: Case Number 220191**
Registration Renewal Application

Dear Thomas Dominy:

Attached is a Notice of Formal Hearing and Statement of Allegations.

Information regarding the following may be found at www.dhp.virginia.gov/Pharmacy/pharmacy_Hearings.htm:

- Frequently Asked Questions about Disciplinary Proceedings;
- Directions to the Department of Health Professions Conference Center;
- Instructions for Requesting Subpoenas;
- The text of the Administrative Process Act;
- The text of all statutes and regulations cited herein.

If you have any questions, you may contact Ellen Shinaberry at (804) 367-4456 Ext 4. or ellen.shinaberry@dhp.virginia.gov. Please notify the Board office of your intent to attend this proceeding.

In the event of inclement weather, please be advised that Board of Pharmacy hearings will be held unless state offices are closed. For information regarding closings or delays, call (804) 367-4400 or go to dhrm.virginia.gov.

Sincerely,

Ellen B. Shinaberry

Ellen B. Shinaberry, RPh, Pharm D
Deputy Executive Director
Virginia Board of Pharmacy

cc: Jess Weber, Adjudication Specialist, Administrative Proceedings Division
Julia K. Bennett, Deputy Director, Administrative Proceedings Division
Katie Land, Senior Investigator, Division of Enforcement
Wayne T. Halbleib, Senior Assistant Attorney General
Karla L. Palmer, Counsel for Respondent
Board Members

**BEFORE THE VIRGINIA BOARD OF PHARMACY**

**IN RE:** **STERRX, LLC, NON-RESIDENT OUTSOURCING FACILITY REWEWAL APPLICANT**

**Registration Number:** 0236-000017
**Issue Date:** April 13, 2017
**Expiration Date:** April 30, 2022
**Case Number:** 220191

## NOTICE OF FORMAL ADMINISTRATIVE HEARING AND STATEMENT OF ALLEGATIONS

**SterRX, LLC is hereby notified that a formal hearing has been scheduled before the Board of Pharmacy ("Board") regarding its registration to act as a non-resident outsourcing facility delivering in the Commonwealth of Virginia.**

| | |
|---|---|
| **TYPE OF PROCEEDING:** | This is a formal administrative hearing before a panel of the Board. |
| **DATE AND TIME:** | **April 19, 2023**<br>**1:00 P.M.** |
| **PLACE:** | Virginia Department of Health Professions<br>Perimeter Center - 9960 Mayland Drive<br>2nd Floor - Virginia Conference Center<br>Henrico, Virginia 23233 |

**LEGAL AUTHORITY AND JURISDICTION:**

1. This formal hearing is being held pursuant to Virginia Code §§ 2.2-4020, 2.2-4024(F), and 54.1-2400(11). This proceeding will be convened as a public meeting pursuant to Virginia Code § 2.2-3700.

2. The burden rests on SterRX. LLC ("Applicant"), as the applicant, to demonstrate that it meet the requirements of Virginia Code § 54.1-3434.5.

3. In considering your application, the Board will consider evidence that grounds exist to deny your application for renewal of your registration to act as a non-resident outsourcing facility, as more fully set out in the enclosed Statement of Allegations.

4. At the conclusion of the proceeding, the Board is authorized to take any of the following actions:

- Approve your application and issue an unrestricted registration to act as a non-resident outsourcing facility;

- Approve your application and issue a reprimand, a monetary penalty, and/or a restricted registration subject to terms and conditions; or

- Deny your application.

**APPLICANT'S LEGAL RIGHTS:**

The non-resident outsourcing facility has the following rights:

- The right to the information on which the Board will rely in making its decision;
- The right to be represented by counsel at this proceeding;
- The right to subpoena witnesses and/or documents;
- The right to present relevant evidence on its behalf.

**ABSENCE OF APPLICANT AND APPLICANT'S COUNSEL:**

If a representative of the non-resident outsourcing facility does not appear at the formal hearing, the Board may proceed to hear this matter in its absence and may take any of the actions outlined above.

**COMMONWEALTH'S EXHIBITS:**

- The Commonwealth's exhibits serve as the basis for the allegations against the non-resident outsourcing facility. The Board will consider these exhibits at the formal hearing.
- These exhibits have been sent to the non-resident outsourcing facility via certified mail/UPS. ***You may be required to sign for these exhibits at the post office.***
- Bring this Notice and the Commonwealth's exhibits to the formal hearing.

**FILING DEADLINES:**

- If you want to submit evidence on your behalf or use expert witnesses, deadlines are below.
- Deadlines for filing any motions or objections to exhibits or expert witness lists are listed below.
- Submit all exhibits, motions, or objections to Ellen Shinaberry at Board of Pharmacy, **9960 Mayland Drive, Suite 300, Henrico, Virginia 23233**.
- Include the case number in all correspondence.

| I. Exhibit Submission | DEADLINE DATE |
|---|---|
| Applicant's Submission of Documents for Evidence (including expert witness reports) (Submit 10 copies) | **March 23, 2023** |
| Commonwealth's Deadline to Respond to Applicant's Submission | **March 29, 2023** |
| Applicant's Deadline to Respond to Commonwealth's Objections | **April 3, 2023** |

**NOTE:** Any documentation or evidence that you previously submitted for an informal conference that is not already part of the Commonwealth's evidence must be resubmitted as an exhibit if you want the Board to consider it at the formal administrative hearing.

| II. Objections to Commonwealth's Exhibits | DEADLINE DATE |
|---|---|
| Applicant's Objections to Commonwealth's Exhibits | **March 29, 2023** |
| Commonwealth's Response to Applicant's Objections | **April 3, 2023** |

**NOTE:** If no objections have been received by March 23, 2023, the exhibits will be distributed to the Board members for their review.

| III. Motions/Continuance Requests | DEADLINE DATE |
|---|---|
| Applicant's Motions | **March 29, 2023** |
| Commonwealth's Response to Motions | **April 3, 2023** |

| IV. Expert Witness Identification | DEADLINE DATE |
|---|---|
| Applicant's Expert Witnesses | **March 29, 2023** |
| Commonwealth's Deadline to Object to Expert Witnesses | **April 3, 2023** |

**NOTE:** If supplementation of expert witness lists is necessary, parties should transmit such supplement to the Board at least five (5) days in advance of the scheduled administrative proceeding. Objections to expert witnesses submitted on a supplemental list may be made prior to or at the hearing for consideration by the Panel Chair.

## STATEMENT OF ALLEGATIONS

The Board alleges that grounds exist to deny the application for renewal of the registration of SterRX, LLC ("Applicant") to act as a non-resident outsourcing facility delivering in the Commonwealth of Virginia in that Applicant violated Virginia Code §§ 54.1-3316(1), (7), and (13) and 54.1-3434.5(C) based on an inspection of the facility between or about September 21 and November 4, 2021, during which investigators from the United States Food and Drug Administration ("FDA") observed instances of noncompliance with the Current Good Manufacturing Practices ("CGMP") as set forth in 21 C.F.R. § 211.1 *et. seq.* of the Code of Federal Regulations, including the following:

1. The air supply for aseptic processing areas was not filtered through high-efficiency particulate air ("HEPA") filters under positive pressure (Observation 1; 21 C.F.R. § 211.42(c)(10)(iii)). Specifically:

a. Applicant had not evaluated the airflow pattern and airborne particulates in the critical processing zones during operations of the Blow-Fill-Seal ("BFS") machines BFS 172 and BFS 321-190 where parisons are cut and the open parisons are shuttled to the point of aseptic filling.

b. The design and construction of the intravenous ("IV") bag filling line on Equipment #E0432, Bausch Type 529, and its enclosure did not provide first-pass HEPA-filtered laminar flow air over all critical areas within the ISO-5 classified zone.

c. First pass HEPA-filtered laminar flow air was obstructed by the glove port and glove and the vibratory bowl over open, partial bags of syringe plungers held adjacent to the vibratory bowl used to hold and convey plungers on the aseptic syringe-filling system.

2. The container closure system did not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product (Observation 2; 21 C.F.R. § 211.94(b)). Specifically:

a. Applicant did not maintain the sterility of the cap and bag interfacing surfaces and the interstitial space making up the container closure of BFS IV bags containing sterile drug products.

b. The container closure was not designed in a way that the user can sanitize the surface(s) before spiking for administration to a patient.

3. Aseptic processing areas were deficient regarding the system for monitoring environmental conditions (Observation 3; 21 C.F.R. § 211.42(c)(10)(iv)). Specifically:

a. The surface and airborne viable monitoring program for aseptic filling operations was not designed and conducted to provide meaningful data to support the quality of the drug products intended to be sterile. Further, Applicant's procedures permit surface and air samples from within ISO 5 environments to yield microbiological contaminants of 1 CFU without conducting an investigation.

b. The airborne particulate monitoring program for aseptic filling operations was not designed and conducted to provide meaningful data to support the quality of the drug products intended to be sterile. Further, Applicant did not monitor airborne particulates to ISO-5 air classifications in all critical locations; the frequency of airborne particulate monitoring was not adequately supported; and the orientation of particle counter probes was not directed into the flow of air in monitored locations.

4. Equipment used in the manufacture, processing, packing, or holding of drug products was not of appropriate design to facilitate operations for its cleaning and maintenance (Observation 4; 21 CFR § 211.63). Specifically, the design and construction of Equipment #E0201, BFS machine 172, incorporated machine parts that were particle generating and difficult to sanitize within the ISO 7 classified zone of the open parison process equipment.

5. Substances required for equipment operations, such as lubricants and coolants, came in contact with components and closures so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements (Observation 5; 21 CFR § 211.65(b)).

Specifically, on the IV Bag filling line, Equipment #E0432, Bausch Type 529, Applicant had not evaluated whether or to what extent solvents and lubricants contained in sterile silicon spray applied to the vibratory bowl of the IV bag filling line, which is intended to produce sterile drug products, transfer to and contaminate IV bag closures (ports). According to manufacturing batch records, during setup and operations of the IV bag filling line, sterile silicon spray is applied onto the stainless steel vibratory bowl to facilitate movement of sterile closures to the filling side of the machine. The records further indicated that the machine may be stopped during the filling operation and more spray may be applied as needed.

6. Applicant failed to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications, whether or not the batch had already been distributed (Observation 6; 21 CFR § 211.192). Specifically, Applicant lacked complete information about environmental conditions in critical areas during aseptic filling operations necessary for investigation and determination of the full product impact and root cause of environmental excursions and drug product sterility failures. The lack of complete environmental data and root cause identification diminished the Applicant's ability to determine and implement effective corrective and preventative actions.

7. Applicant's procedures for cleaning and maintenance of equipment did not include protection of clean equipment from contamination prior to use (Observation 7; 21 CFR § 211.67(b)(5)). Specifically, the SOP does not specify for how long equipment that has been sterilized in Hotpack oven #E0333 may remain in the transition zone wrapped in foil after being removed from the oven but prior to use.

8. Applicant's procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process (Observation 8; 21 CFR § 211.113(b)).

9. Protective apparel was not worn as necessary to protect drug products from contamination. Specifically, Applicant permits personnel to enter packaging areas and conduct packaging operations in their street clothes and footwear (Observation 9; 21 CFR § 211.28(a)).

10. The written stability program for drug products did not include meaningful test methods (Observation 10; 21 CFR § 211.166(a)(3)). Specifically, the stability program, "SOP-VAL-0097" did not evaluate the photostability of light-sensitive drug products in the marketed packaging. Although, in accordance with the Applicant's protocols, the stability samples remained within their marketed secondary packaging consisting of foil-lined pouches throughout the hold time, Applicant lacked sufficient evidence through direct testing to show that the secondary packaging adequately protects drug products from light.

11. Personnel were not trained in the particular operations they performed as part of their assigned function (Observation 11; 21 CFR § 211.25(a)). Specifically, records indicated that two operators participated in the aseptic production of batches of drugs prior to being certified to perform production independently, accurately, and in compliance with the CGMP.

12. Complaint records do not include the known reply to a complainant. Specifically, complainants do not always receive a final written response to their drug product complaint (Observation 12; 21 CFR § 211.198(b)(1)).

Ellen B. Shinaberry

Ellen B. Shinaberry, RPh, Pharm D.
Deputy Executive Director
Virginia Board of Pharmacy

1/13/2023
Date

IFIC Surety
A Member of IAT Insurance Group

***HARCO NATIONAL INSURANCE COMPANY***

CONTINUATION CERTIFICATE

Bond No: 0736296 Bond Amount: $25,000
Term: 10/14/22 to 10/14/23

Principal: STERRX LLC
141 IDAHO AVE
PLATTSBURGH, NY 12903

Obligee: Nevada State Board of Pharmacy

Agent: Lockton Companies, LLC.
Suite 3400
500 W. Monroe St.
Chicago, IL 60661

It is hereby agreed that the captioned numbered Bond continued in force in the above amount for the period of the continued term stated above.

This continuation shall be deemed a part of the original bond and not a new obligation and is subject to all the covenants and conditions of said bond.

HARCO NATIONAL INSURANCE COMPANY CORPORATE SEAL 1984 ILLINOIS

HARCO NATIONAL INSURANCE COMPANY

By: Valentina A. Gaskill
Valentina A. Gaskill / Authorized Representative

# Nevada State Board Of Pharmacy

## Payment Confirmation

Dear STER RX LLC,

Your payment has been processed successfully. Below are the details:

| | | | |
|---|---|---|---|
| Applicant ID#: | **93475** | Reference#: | **64265379608** |
| Payment Method: | **Credit Card** | Invoice#: | **509671** |
| Transaction Date: | **03/20/23** | Total Fees: | **$1050.00** |
| Transaction Time: | **11:06:39 AM** | | |

Total amount paid: **$1050.00**

Fee Details

| **Description** | **Fee Type** | **Fees** |
|---|---|---|
| REGISTRATION:Wholesaler (1015) | REGISTRATION:Wholesaler (1015) | 1050.00 |
| | **Total** | **$1050.00** |

This email is an automated notification, which is unable to receive replies. We are happy to help you with any questions or concerns you may have. If you have questions mail to bop@nv.gov.

Thank you,

Nevada State Board Of Pharmacy

http://bop.nv.gov/

DocuSign Envelope ID: FE79A3CA-33B1-4F4E-B5D7-B3A8463D298C

SterRx® STERILE MANUFACTURER OF 503B COMPOUNDED DRUGS

**SterRx, LLC**
141 IDAHO AVENUE
PLATTSBURGH, NY 12903
844.319.7799

May 12, 2023

To Whom it May Concern:

**SUBJECT: Change of Pharmacist in Charge and Designated Representative at SterRx, LLC**

Please be notified that a Change of Pharmacist in Charge and Designated Representative will be in effect at the following facility on **June 1, 2023**:

SterRx, LLC
141 Idaho Avenue
Plattsburgh, New York 12903

Pharmacist in Charge and Designated Representative to be removed:
Thomas Dominy: NY license #056883
Pharmacist in Charge to be added:
Rosanna Ressing: NY license #058066-01
Designated Representative to be added:
Sarah McCoy, Director of Plant Operations

SterRx, LLC's facility management will remain the same:

Sarah McCoy, Director of Plant Operations
[redacted] Idaho Avenue
Plattsburgh, New York 12903
Ph: 1[redacted]

Jerry Webb, EVP Global Operations
[redacted] N. Roselle Road, suite [redacted]
Schaumburg, Illinois 60195
Ph: 1-[redacted]

Day-to-day operations will remain uninterrupted, continuing with business as usual, under the same:

Federal Tax ID Number: 61-1718460
DUNS Number: 049167014
FDA Establishment Number: 30-10840309

DEA Registration Number: RS0547591
NYSED: Outsourcing Facility: 034102
NY DoH Controlled Substance: 100223

SterRx, LLC will be submitting the appropriate documentation on a state-by-state basis. Should additional information be required, or if further action is required by SterRx, LLC, please do not hesitate to contact us.

Sincerely,

DocuSigned by:
Sarah J. McCoy
9D3DC917C42A464...
Sarah McCoy

cc: Jerry Webb

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

**Section 1: Pharmacy/Wholesaler Information**

Name of Pharmacy/Wholesaler SterRx, LLC

Pharmacy/Wholesaler License # (if applicable) WH02253

Physical Address 141 Idaho Ave

City Plattsburgh State NY Zip 12903

Mailing Address (if different from physical address) as above

City _____ State _____ Zip _____

Telephone 1-518-324-7879 Website www.sterrx.com

Licensing Company Email truenorthconsultingiowa@gmail.com

**Section 2: Personal Information**

First Sarah Middle Jayne Last McCoy

Alias(es, nicknames, name changes, etc.) Maiden Name: Plishka

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]daho Ave

City Plattsburgh State NY Zip 12903

Telephone 1-518-324-7879 Email sarah.mccoy@sterrx.com

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| | | | |
|---|---|---|---|
| School Name: University of Phoenix | | | From - To (MM/YY – MM/YY): 2005 - 2007 |
| Address: Online | City: | State: | Zip: |
| Diploma/Degree obtained, if any: MBA | | | |
| School Name: State University of New York at Plattsburgh | | | From - To (MM/YY – MM/YY): 1997 - 2000 |
| Address: 101 Broad St. | City: Plattsburgh | State: NY | Zip: 12901 |
| Diploma/Degree obtained, if any: BS Cellular Biochemistry | | | |
| School Name: Champlain Valley Educational Services | | | From - To (MM/YY – MM/YY): 2010 - 2011 |
| Address: 1443 Military Turnpike | City: Plattsburgh | State: NY | Zip: 12901 |
| Diploma/Degree obtained, if any: Licensed Practical Nursing | | | |
| School Name: | | | From - To (MM/YY – MM/YY): |
| Address: | City: | State: | Zip: |
| Diploma/Degree obtained, if any: | | | |
| School Name: | | | From - To (MM/YY – MM/YY): |
| Address: | City: | State: | Zip: |
| Diploma/Degree obtained, if any: | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 2018-now | [redacted]LAKEVIEW DR | PLATTSBURGH | NY | 12901 |
| 2012-2018 | [redacted]JOANNE LN | CADYVILLE | NY | 12918 |
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**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| | | | | |
|---|---|---|---|---|
| Business Name: SterRx, LLC | | | | From - To (MM/YY – MM/YY): 2013 - present |
| Business Address: 141 Idaho Ave | | City: Plattsburgh | State: NY | Zip: 12903 |
| Phone: 1-518-324-7879 | Title: Director, Plant Operations | | | Number of Employed Hours: 24,000 |
| Description of Duties: Responsible for directing, managing and coordinating all activities associated with a 503B pharmaceutical company. Ensure personnel comply with all applicable federal, state and local regulations as issued by the FDA, EPA, OSHA, DEA | | | | |

| | | | | |
|---|---|---|---|---|
| Business Name | | | | From - To (MM/YY – MM/YY) |
| Business Address | | City | State | Zip |
| Phone | Title | | | Number of Employed Hours |
| Description of Duties | | | | |

| | | | | |
|---|---|---|---|---|
| Business Name | | | | From - To (MM/YY – MM/YY) |
| Business Address | | City | State | Zip |
| Phone | Title | | | Number of Employed Hours |
| Description of Duties | | | | |

| | | | | |
|---|---|---|---|---|
| Business Name | | | | From - To (MM/YY – MM/YY) |
| Business Address | | City | State | Zip |
| Phone | Title | | | Number of Employed Hours |
| Description of Duties | | | | |

| | | | | |
|---|---|---|---|---|
| Business Name | | | | From - To (MM/YY – MM/YY) |
| Business Address | | City | State | Zip |
| Phone | Title | | | Number of Employed Hours |
| Description of Duties | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper If additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | ✔ | |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # 6 . Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| 11/02/2022 | | VA | Henrico | Henrico |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| 220191 | | Virginia Board of Pharmacy | | |
| **Reason/Charge** | | | | |
| Informal Conference, re: FDA Form 483: dated November 4, 2021 | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | **Lawsuit/Arbitration/Bankruptcy** | | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| SterRx, LLC | | | | |

**Provide explanation below:**

Formal Hearing requested by SterRx, LLC on December 5, 2022.
Formal Hearing date to be confirmed by Virginia Board of Pharmacy.
Allegation Summary Worksheet attached.

Sarah A. McCoy
Original Signature (electronic, copies or stamps not accepted)

17 May 2023
Date

I, Sarah McCoy, **certify that as the designated representative for**

SterRx, LLC,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. SM I am at least 21 years of age;
3. SM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Sarah McCoy

Print Name (First, Last)

Sarah A McCoy

Original Signature (electronic, copies or stamps not accepted)

17 May 2023

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Sarah McCoy

Print Name (First, Last)

Sarah A. McCoy

Original Signature (electronic, copies or stamps not accepted)

17 May 2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of New York, ss. County of Clinton

I, Sarah McCoy, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Sarah A. McCoy

**Original Signature**

17 May 2023

**Date**

Subscribed and Sworn to before me this 17 day of MAY 2023

**Notary Public Signature**

CODIE PARNABY
Notary Public, State of New York
Qualified in Clinton County
Reg. No. 01PA6382051
My Commission Expires 10/15/2026

(Seal)

DocuSign Envelope ID: 1FB5BC6F-485F-46E4-87ED-BAC9252EBD8B

SterRx® STERILE MANUFACTURER OF 503B COMPOUNDED DRUGS

**SterRx, LLC**
141 IDAHO AVENUE
PLATTSBURGH, NY 12903
844.319.7799

# MEMO

Date: May 19, 2023

To: Whom it May Concern

From: SterRx, LLC
141 Idaho Avenue
Plattsburgh, NY 12903

Subject: Pending Disciplinary Action

Memo:

A Formal Hearing with the Virginia Board of Pharmacy, re: Case #220191, was scheduled for April 19, 2023. The Hearing has been postponed. At this date, the Virginia Board of Pharmacy has not set a new Hearing date. The expected Hearing date is between August and late October 2023.

Should additional information be required, please do not hesitate to contact us.

DocuSigned by:
Sarah J. McCoy
9D30C917C42A464...
Sarah McCoy
Director of Plant Operations

cc: Rosanna Ressing
Sr Pharmacy Manger
cc: Jerry Webb
EVP Operations, Sagent Pharmaceuticals
cc: Karla Palmer
Hyman, Phelps & McNamara, P.C.

# COMMONWEALTH of VIRGINIA

Arne W. Owens
Director

*Department of Health Professions*
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

www.dhp.virginia.gov
PHONE (804) 367-4400

**Board of Pharmacy**
**804/367-4456**
**804-527-4472 (fax)**

January 24, 2023

Certified Article Number
9414 7266 9904 2198 8144 95
SENDER'S RECORD

**Return receipt requested**

Received 30 Jan 23
TD 30 Jan 23

Thomas Dominy, Pharmacist-in-Charge
SterRX, LLC
141 Idaho, Avenue
Plattsbrgh, NY 12903

**RE: Case Number 220191**

Dear Thomas Dominy:

This is to advise you that the Allegation Summary Worksheet was inadvertently left out of the packet previously mailed to you, pertaining to your scheduled Formal Hearing for April 19, 2023 at 1:00 P.M. at the Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Suite 201, Henrico, Virginia. Please find the Allegation Summary Worksheet enclosed.

Sincerely,

Ellen B. Shinaberry

Ellen B. Shinaberry, RPh, Pharm D.
Deputy Executive Director
Virginia Board of Pharmacy

## ALLEGATION SUMMARY WORKSHEET

Page numbers of the documents that most clearly support the allegations are referenced here and are not intended to be inclusive. There may be additional supporting documents in the report that are not referenced here.

**Name:** SterRX, LLC **Registration No.:** 0236-000017
**Case No.:** 220191

| ALLEGATIONS | SUPPORTING PAGE NUMBERS (ALL IN CW'S EXHIBIT 2) |
|---|---|
| Applicant violated Virginia Code §§ 54.1-3316(1), (7), and (13) and 54.1-3434.5(C) based on an inspection of the facility between or about September 21 and November 4, 2021, during which investigators from the United States Food and Drug Administration ("FDA") observed instances of noncompliance with the Current Good Manufacturing Practices ("CGMP") as set forth in 21 C.F.R. § 211.1 *et. seq.* of the Code of Federal Regulations, including the following:<br>1. The air supply for aseptic processing areas was not filtered through high-efficiency particulate air ("HEPA") filters under positive pressure (Observation 1; 21 C.F.R. § 211.42(c)(10)(iii)). Specifically:<br>a. Applicant had not evaluated the airflow pattern and airborne particulates in the critical processing zones during operations of the Blow-Fill-Seal ("BFS") machines BFS 172 and BFS 321-190 where parisons are cut and the open parisons are shuttled to the point of aseptic filling.<br>b. The design and construction of the intravenous ("IV") bag filling line, Equipment #E0432, Bausch Type 529, and its enclosure did not provide first-pass HEPA-filtered laminar flow air over all critical areas within the ISO-5 classified zone.<br>c. First pass HEPA-filtered laminar flow air was obstructed by the glove port and glove and the vibratory bowl over open, partial bags of syringe plungers held adjacent to the vibratory bowl used to hold and convey plungers on the aseptic syringe-filling system. | • P. 10-13, 56-97, 65-70 |
| 2. The container closure system did not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product (Observation 2; 21 C.F.R. § 211.94(b)). Specifically:<br>a. Applicant did not maintain the sterility of the cap and bag interfacing surfaces and the interstitial space making up the container closure of BFS IV bags containing sterile drug products.<br>b. The container closure was not designed in a way that the user can sanitize the surface(s) before spiking for administration to a patient. | • P. 13-14, 56-97, 70-72 |
| 3. Aseptic processing areas were deficient regarding the system for monitoring environmental conditions (Observation 3; 21 C.F.R. § 211.42(c)(10)(iv)). Specifically:<br>a. The surface and airborne viable monitoring program for aseptic filling operations was not designed and conducted to provide meaningful data to support the quality of the drug products intended to be sterile. Further, Applicant's procedures permit surface and air samples from within ISO 5 environments to yield microbiological contaminants of 1 CFU without conducting an investigation. | • P. 14-22, 56-97, 72-79 |

| | |
|---|---|
| b. The airborne particulate monitoring program for aseptic filling operations was not designed and conducted to provide meaningful data to support the quality of the drug products intended to be sterile. Further, Applicant did not monitor airborne particulates to ISO-5 air classifications in all critical locations; the frequency of airborne particulate monitoring was not adequately supported; and the orientation of particle counter probes was not directed into the flow of air in monitored locations. | |
| 4. Equipment used in the manufacture, processing, packing, or holding of drug products was not of appropriate design to facilitate operations for its cleaning and maintenance (Observation 4; 21 CFR § 211.63). Specifically, the design and construction of Equipment #E0201, BFS machine 172, incorporated machine parts that were particle generating and difficult to sanitize within the ISO 7 classified zone of the open parison process equipment. | • P. 22-23, 56-97, 79-80 |
| 5. Substances required for equipment operations, such as lubricants and coolants, came in contact with components and closures so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements (Observation 5; 21 CFR § 211.65(b)). Specifically, on the IV Bag filling line, Equipment #E0432, Bausch Type 529, Applicant had not evaluated whether or to what extent solvents and lubricants contained in sterile silicon spray applied to the vibratory bowl of the IV bag filling line, which is intended to produce sterile drug products, transfer to and contaminate IV bag closures (ports). According to manufacturing batch records, during setup and operations of the IV bag filling line, sterile silicon spray is applied onto the stainless steel vibratory bowl to facilitate movement of sterile closures to the filling side of the machine. The records further indicated that the machine may be stopped during the filling operation and more spray may be applied as needed. | • P. 23, 56-97, 80 |
| 6. Applicant failed to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications, whether or not the batch had already been distributed (Observation 6; 21 CFR § 211.192). Specifically, Applicant lacked complete information about environmental conditions in critical areas during aseptic filling operations necessary for investigation and determination of the full product impact and root cause of environmental excursions and drug product sterility failures. The lack of complete environmental data and root cause identification diminished the Applicant's ability to determine and implement effective corrective and preventative actions. | • P. 23-29, 56-97, 81-88 |
| 7. Applicant's procedures for cleaning and maintenance of equipment did not include protection of clean equipment from contamination prior to use (Observation 7; 21 CFR § 211.67(b)(5)). Specifically, the SOP does not specify for how long equipment that has been sterilized in Hotpack oven #E0333 may remain in the transition zone wrapped in foil after being removed from the oven but prior to use. | • P. 29-30, 56-97, 88-89 |
| 8. Applicant's procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process (Observation 8; 21 CFR § 211.113(b)). | • P. 30-31, 56-97, 89-90 |

| | |
|---|---|
| 9. Protective apparel was not worn as necessary to protect drug products from contamination. Specifically, Applicant permits personnel to enter packaging areas and conduct packaging operations in their street clothes and footwear (Observation 9; 21 CFR § 211.28(a)). | • P. 31-32, 56-97, 90-91 |
| 10. The written stability program for drug products did not include meaningful test methods (Observation 10; 21 CFR § 211.166(a)(3)). Specifically, the stability program, "SOP-VAL-0097" did not evaluate the photostability of light-sensitive drug products in the marketed packaging. Although, in accordance with the Applicant's protocols, the stability samples remained within their marketed secondary packaging consisting of foil-lined pouches throughout the hold time, Applicant lacked sufficient evidence through direct testing to show that the secondary packaging adequately protects drug products from light. | • P. 32, 56-97, 92 |
| 11. Personnel were not trained in the particular operations they performed as part of their assigned function (Observation 11; 21 CFR § 211.25(a)). Specifically, records indicated that two operators participated in the aseptic production of batches of drugs prior to being certified to perform production independently, accurately, and in compliance with the CGMP. | • P. 32-33, 56-97, 92-94 |
| 12. Complaint records do not include the known reply to a complainant. Specifically, complainants do not always receive a final written response to their drug product complaint (Observation 12; 21 CFR § 211.198(b)(1)). | • P. 33-35, 56-97, 94-96 |

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

**Section 1: Pharmacy/Wholesaler Information**

Name of Pharmacy/Wholesaler SterRx, LLC

Pharmacy/Wholesaler License # (if applicable) WH02253

Physical Address 133 Connecticut Road

City Plattsburgh State NY Zip 12903

Mailing Address (if different from physical address) 141 Idaho Avenue

City Plattsburgh State NY Zip 12903

Telephone 1-518-324-7879 Website www.sterrx.com

Licensing Company Email truenorthconsultingiowa@gmail.com

**Section 2: Personal Information**

First Karen Middle Ann Last Greene

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted] Idaho Avenue

City Plattsburgh State NY Zip 12903

Telephone [redacted] Email karen.greene@sterrx.com

Are you a citizen of the United States? ☑ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✔ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Clinton Community College | | Grad date 12/2013 | |
| Address | City | State | Zip |
| 136 Clinton Point Drive | Plattsburgh | NY | 12901 |
| Diploma/Degree obtained, if any | | | |
| Associate of Applied Science Degree | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Northeastern Clinton Central School | | 1976 - 1980 | |
| Address | City | State | Zip |
| 103 Route 278 | Champlain | NY | 12901 |
| Diploma/Degree obtained, if any | | | |
| High School Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| N/A | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| N/A | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 02/12 - current | [redacted] Lake Shore Road | Chazy | NY | 12921 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| N/A | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| N/A | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| N/A | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| N/A | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| N/A | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| N/A | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| N/A | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| N/A | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| N/A | | | | |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| SterRx, LLC | | | 02/09/2015 - present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 133 Connecticut Avenue | | Plattsburgh | NY | 12903 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 1-518-324-7879 | Associate Director of Materials Management | | 18,840 | |
| **Description of Duties** | | | | |
| Responsible for overseeing the warehouse areas and that finished products are delivered in a timely manner. Ensuring that all safety practices are in compliance with pertinent and applicable regulatory requirements. | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| N/A | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| N/A | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| N/A | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

Continue on next page if additional space is needed.

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name<br>N/A | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name<br>N/A | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name<br>N/A | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✔ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✔ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✔ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✔ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✔ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✔ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✔ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✔ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✔ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✔ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question #** N/A **. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| N/A | N/A | N/A | N/A | N/A |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| N/A | | N/A | | |
| **Reason/Charge** | | | | |
| N/A | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| N/A | | | N/A | |
| **Name of Business/Industry/Entity** | | | | |
| N/A | | | | |

**Provide explanation below:**

N/A

Karen D. Greene
Original Signature (electronic, copies or stamps not accepted)

15 Jun 23
Date

I, Karen Ann Greene, **certify that as the designated representative for**

SterRx, LLC,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. _____ I am at least 21 years of age;
3. _____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. _____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. _____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. _____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. _____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Karen Green

Print Name (First, Last)

Karen A. Greene

Original Signature (electronic, copies or stamps not accepted)

15 Jun 23

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Karen Greene

Print Name (First, Last)

Karen A. Greene — 15 Jun 23

Original Signature (electronic, copies or stamps not accepted) — Date

---

**Please have this section completed in the presence of a Notary Public.**

State of New York, ss. County of Clinton

I, Cindy Caner, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Karen A. Greene — 15 Jun 23

**Original Signature** — **Date**

Subscribed and Sworn to before me this 15 day of June 2023

Cindy Caner

**Notary Public Signature**

Cindy Caner
Notary Public, State of New York
No. 01CA6264000
Qualified in Essex County
My Commission Expires 06/25/2024

**(Seal)**

# 12

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Wholesaler Application

**Non-Refundable $1,000 Fee**

Rev (08/17/2022)

| Where is the facility located? | ■ Nevada ☐ Out-of-State |
|---|---|

| Type of Application (check applicable box) | | Wholesaler Business Type (check applicable box) |
|---|---|---|
| ■ New Wholesaler<br>☐ Ownership Change*<br>☐ Name Change*<br>☐ Location Change* (in-state only) | * If making a change, provide current license number:<br>WH _____ | ☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)<br>■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)<br>☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)<br>☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9) |

**Section 1: General Information**

Facility Name: Reliable Healthcare Logistics, LLC

Physical Address: 1175 Trademark Drive, Suite 101

City: Reno State: NV Zip: 89521

Mailing Address (if different from physical address): 951 Clint Moore Road, Suite A

City: Boca Raton State: FL Zip: 33487

Telephone: (775) 376-1121 x451 Website: https://www.reliablehealthcarelogistics.com/

Name of Designated Representative (DR): Casey Brown

Licensing Company Email: 1175license@reliablehealthcarelo[illegible] DR Email: cbrown@rhcl3pl.com

| Entities the Wholesaler will Serve (✓ all applicable) | Products to be Handled or Wholesaled (✓ all applicable) | Type of Wholesaling (✓ all applicable) |
|---|---|---|
| ☐ Pharmacies | ☐ Dangerous Drugs | ☐ Manufacturer |
| ☐ Practitioners | ☐ Controlled Substances | ☐ Repacker |
| ☐ Hospitals | ☐ [a]Medical devices, equipment, supplies, gases | ☐ Reverse Distributor |
| ■ Wholesalers | ■ Others: OTC Drugs, Nutritional Supplements | ■ Warehouse |
| ☐ Veterinarians | | ■ Retail pharmacy wholesale distributor |
| ☐ Others: | | ☐ Others: |

| Section 2: History of Company | Yes | No |
|---|---|---|
| 1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? | | ✓ |
| 2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? | | ✓ |
| 3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? | | ✓ |
| 4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? | | ✓ |
| 5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? | | ✓ |

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

**Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.**

Name: NBTY Global, Inc., ("NBTY")
Address: 2100 Smithown Avenue City: Ronkonkoma State: NY Zip: 11779
Name: OK Capsule, Inc.
Address: 725 Trademark Drive, Unit 104 City: Reno State: NV Zip: 89521
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

**Section 4: Publicly Traded Corporation**

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

| Date of SEC Registration: | SEC Registration Number: | Stock Exchange Symbol: |
|---|---|---|

**Section 5: Non-Publicly Traded Corporation or Company**

State of Incorporation/Organization: Delaware
Parent Company (if any):
Corporation/Organization Name: Reliable Healthcare Logistics, LLC
Mailing Address: 951 Clint Moore Road, Suite A
City: Boca Raton State: FL Zip: 33487
Telephone: 561-998-3885 Ext 216 Email: 1175license@reliablehealthcarelogistics.com
Contact Person Name: Lizbeth Hernandes

**Section 6: Partnership**

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

**Section 7: Sole Owner**

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

| Section 8: NABP Accreditation/FDA Registration | Yes | No |
|---|---|---|
| Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide: | | ✔ |
| 1. Copy of Certification<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |
| Is your company licensed as a Manufacturer by the FDA? If yes, provide: | ✔ | |
| 1. Copy of FDA registration<br>2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. | | |

| Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right. | Publicly Traded | Non-publicly Traded | Partnership | Sole Owner |
|---|---|---|---|---|
| • **List of all Officers and Directors.** | ✓ | ✓ | | |
| • **List the top four corporation shareholders and their percent ownership.** | ✓ | | | |
| • **List of all corporation shareholders and their percent ownership.** | | ✓ | | |
| • **List of all partners and their percent ownership.** | | | ✓ | |
| • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** | ✓ | ✓ | ✓ | ✓ |
| • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ | | ✓ | ✓ | ✓ |
| • **Copy of DEA certificate if handling controlled substances** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of current SEC 10K or 8K** (First 15 pages only) | ✓ | | | |
| • **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** | ✓ | ✓ | ✓ | ✓ |
| • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** | ✓ | ✓ | ✓ | ✓ |
| • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ | ✓ | ✓ | ✓ | ✓ |
| • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). | ✓ | ✓ | ✓ | ✓ |
| **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)** | | | | |
| • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. | | ✓ | ✓ | ✓ |
| • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. | | ✓ | ✓ | ✓ |

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.**

Reliable Healthcare Logistics, LLC

Facility Name

Tyler Kattawar

Print Name of Authorized Person Submitting Application

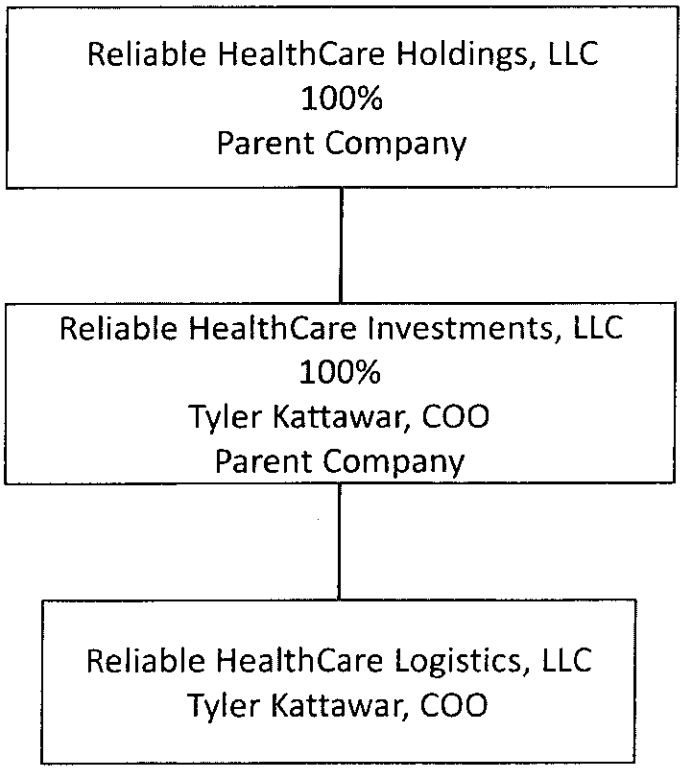
Original signature of Authorized Person (copies or stamps not accepted)

2/2/2023

Date

| Board Use Only | Date Received: 2·28·23 | Amount: 1000.00 CK: 10958 |
|---|---|---|

Reliable HealthCare Logistics, LLC – Entity Organization Chart



SECRETARY OF STATE

STATE OF NEVADA

# NEVADA STATE BUSINESS LICENSE

**Reliable HealthCare Logistics, LLC**

**Nevada Business Identification # NV20232731584**

**Expiration Date: 03/31/2024**

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
**License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.**

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 05/26/2023.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202305263683048
You may verify this certificate online at http://www.nvsos.gov

# Delaware

The First State



I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "RELIABLE HEALTHCARE LOGISTICS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-THIRD DAY OF FEBRUARY, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "RELIABLE HEALTHCARE LOGISTICS, LLC" WAS FORMED ON THE FOURTH DAY OF MARCH, A.D. 2022.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN ASSESSED TO DATE.

Jeffrey W. Bullock, Secretary of State

6655021 8300

SR# 20230652279

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202769958

Date: 02-23-23

# Reliable HealthCare Logistics, LLC

Name: Tyler Kattawar as the Chief Operation Officer and Manager of the LLC.

Telephone: 901-603-7539

Logistics Manager: Casey Brown

Designated Representative: Casey Brown

List of Officers and Directors:

1. Robert Gerstein, President – 951 Clint Moore Road, Suite A, Boca Raton, FL 33487 – 561-998-3885 Ext 204
2. Michael Mackay, COO – 951 Clint Moore Road, Suite A, Boca Raton, FL 33487 – 561-998-3885 Ext 201
3. Cheryl Oleski, Director of Quality – 951 Clint Moore Road, Suite A, Boca Raton, FL 33487 Ext 307

1175 Trademark Drive, Suite 101, Reno, NV 89521

| Department: 008 - Reno Nevada | |
|---|---|
| 2/22/2023 | Albert, Jaycob L |
| 2/22/2023 | Barker, Keith A |
| 2/22/2023 | Brown, Casey C |
| 2/22/2023 | Eells Richardson, Marcus D |
| 2/22/2023 | Ferguson, Tyler T |
| 2/22/2023 | Miner, Macy R |
| Reno Nevada: 6 | |

# LEADERSHIP TEAM



Rob Gerstein
President



Cheryl Oleski *
Director of Quality



Carl Ambroise
Director of Information Technology



Melissa Gallagher
Human Resources Manager



Jeff James
VP Business Development



Michael MacKay
Chief Operating Officer

Reliable HealthCare Logistics

* Quality Representative

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

# Drug Establishments Current Registration Site

New Search (default.cfm)

Search Results for **Reliable HealthCare Logistics, LLC**

CSVExcel

Filter: 1175

| Firm Name | FDA Establishment Identifier | DUNS | Business Operations | Address | Expiration Date |
|---|---|---|---|---|---|
| Reliable Healthcare Logistics, LLC | | 118890241 | RELABEL; REPACK; | 1175 Trademark Dr Ste 101, Reno, Nevada (NV) 89521, United States (USA) | 12/31/2023 |

Showing 1 to 1 of 1 entries (filtered from 9 total entries)
Previous1Next
Data Current through: Friday, Mar 17, 2023

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Designated Representative Application

Rev (05/12/2022)

Name of Pharmacy/Wholesaler Reliable Healthcare Logistics, LLC

Pharmacy/Wholesaler License # (if applicable) N/A

Physical Address 1175 Trademark Drive, Suite 101

City Reno State NV Zip 89521

Mailing Address (if different from physical address) 951 Clint Moore Road, Suite A

City Boca Raton State FL Zip 33487

Telephone _____ Website www.reliablehealthcarelogistics.com

Licensing Company Email 1175License@reliablehealthcarelogistics.com

First Casey Middle Christine Last Brown

Alias(es, nicknames, name changes, etc.) Casey Tewell (maiden)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted] Homann Way

City Carson City State NV Zip 89703

Telephone [redacted] Email cbrown@rhcl3pl.com

Are you a citizen of the United States? ☑ Yes ☐ No

| | | |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| | | |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Sierra High School | | 08/05 - 05/09 | |
| Address | City | State | Zip |
| | Manteca, CA | | |
| Diploma/Degree obtained, if any | | | |
| Diploma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 06/22 - Present | [redacted] Homann Way | Carson City | NV | 89703 |
| 3/20 - 06/22 | [redacted] Pintail Drive | Carson City | NV | 89701 |
| 06/18 - 03/20 | [redacted] Overland Loop | Dayton | NV | 89430 |
| 01/18 - 06/18 | [redacted] Arizona Circle | Carson City | NV | 89701 |
| 11/17 - 1/18 | [redacted] Compass Lane | Manteca | CA | 95337 |
| 11/16 - 11/17 | [redacted] N Locust Ave | Ripon | CA | 95366 |
| 1/14 - 11/16 | [redacted] W Ripon Rd | Ripon | CA | 95366 |
| 10/12 - 01/14 | [redacted] San Juan St | Manteca | CA | 95336 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| | | | | |

**Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Reliable HealthCare Logistics, LLC | | | 08/11/2022 - Present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 1175 Trademark Drive, Suite 101 | | Reno | NV | 89521 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 775-376-1121 Ext 451 | Facility Manager | | 1,040.00 | |
| **Description of Duties** | | | | |
| Responsible for the daily warehouse operations. Responsible for performing specific warehouse functions for receiving, storage, inventory management, order processing, fulfilment, transportation, and reporting. | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Woofield Distribution, LLC | | | 10/21- 08/2022 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 1175 Trademark Drive, Suite 101 | | Reno | NV | 89521 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 775-376-1121 Ext 451 | Logistics Manager | | 1,733.33 | |
| **Description of Duties** | | | | |
| Responsible for performing specific warehouse functions for receiving, storage, inventory management, order processing, fulfilment, transportation, and reporting. | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Juice Plus Co | | | 04/2021 - 10/2021 | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | Sparks | NV | 89431 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | Distribution Center Manager | | 1,040.00 | |
| **Description of Duties** | | | | |
| Responsible for all aspects of managing the Sparks Distribution Center from Maintenance, Operations, Supply Chain, HR and more | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Pure Ground Ingredients, Inc | | | 08/2020 - 04/2021 | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | Minden | NV | 89423 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | Project Manager & Inventory Controller | | 1,386.66 | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Aloha Medicinals | | | 02/2019 - 08/2020 | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | Carson | NV | 89706 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | Warehouse Manager & Inventory Controller | | 3,120.00 | |
| **Description of Duties** | | | | |
| | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Business Address | | City | State | Zip |
| Phone | Title | | Number of Employed Hours | |
| Description of Duties | | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| | | |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✓ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✓ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✓ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✓ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| | |

| Reason/Charge |
|---|
| |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

2/22/23
Date

I, Casey Brown **, certify that as the designated representative for**

Reliable HeatlhCare Logistics, LLC ,

**that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. C.B. I am at least 21 years of age;
3. C.B. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. C.B. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. C.B. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. C.B. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. C.B. I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Casey Brown

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/22/23

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Casey Brown
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/22/23
Date

---

**Please have this section completed in the presence of a Notary Public.**

State of Nevada, ss. County of Washoe

I, Casey Brown, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

2/22/23
**Date**

Subscribed and Sworn to before me this 22nd day of February 2023.

Tami L Thompson
**Notary Public Signature**

TAMI L. THOMPSON
Notary Public - State of Nevada
County of Washoe
APPT. NO. 19-3144-02
My App. Expires Oct. 18, 2023
(Seal)

[redacted] Homann Way, Carson City, NV 89703 • [redacted] • [redacted]

# Casey Brown

## Summary

Respected leader, able to build a highly motivated team focused on achieving productivity goals. A Professional Warehouse Manager with over 7 years of experience in warehousing, inventory control, supply chain and logistics. 11 years of customer service experience has built a foundation of providing excellent service to internal customers and developing great repour with outside vendors and service providers. As a professional, I am dedicated to improving customer satisfaction through operations and increasing productivity company wide.

## Experience

### Logistics Manager: October 2021 – Present
### Reliable HealthCare Logistics, LLC. (Formerly Woodfield Distribution) – Sparks, NV 89431

### Distribution Center Manager: April 2021 – October 2021
### Juice Plus Co. – Sparks, NV 89431

- Responsible for all aspects of managing the Sparks Distribution Center from Maintenance, Operations, Supply Chain, HR and more.
- Meet the shipping and quality goals for the west coast distribution set by the main Distribution Center in Memphis.
- Set and measure all KPI's for the location and the individuals employed at the facility.
- Created a training program to educate staff on lean manufacturing and 5S methodologies.

### Project Manager & Inventory Controller: August 2020 – April 2021
### Pure Ground Ingredients, Inc. – Minden, NV 89423

- Implemented a cycle count program after reviewing usage by item and identifying A, B and C items.
- Identified root causes for inventory inaccuracies, implemented solutions and brought inventory accuracy from 89% to 98% and have maintained it through measuring and root cause analysis.
- Implemented the NetSuite ERP system successfully as the company's first Project Manager.
- In addition to implementing the ERP system, advanced WMS and Manufacturing Routers were set up to maximize efficiency and delivery.
- Put companywide KPI measurements in place starting with inventory, OTD and efficiency.

### Warehouse Manager & Inventory Controller: February 2019 – August 2020
### Aloha Medicinals - Carson City, NV 89706

- Managed the shipping team and exceeded the OTD goal of 96% OTD.
- Managed shipments and logistics during the company's move to new warehouse.
- Strategically mapped out the new shipping department with a "U" shaped flow to maximize productivity and efficiency at the new warehouse location.
- Improved the company's inventory accuracy from 28% to 98% over the course of 6 months.

775-430-1624 • caseybrown082021@gmail.com

# Casey Brown

### Customer Service & Supply Chain Manager: March 2018 – February 2019

### Aloha Medicinals - Carson City, NV 89706

- Improved on time deliveries by 17% over the course of 4 months. Identified specific problem areas and resolved each one in a timely manner to improve workflow, accuracy and customer satisfaction.
- Promoted from Customer Service & Supply Chain Manager to Warehouse Manager & Inventory Controller after 11 months.
- Scheduled jobs for the production teams to maximize safety stock levels based on usage, lead time and warehouse space.
- Improved supply chain processes and eliminated waste in the department.

### Shipping Manager: April 2015 –February 2018

### BR Funsten & Tom Duffy Co. - Manteca, CA

- Expanded and improved the services provided by our company's shipping department. Created the company's Hazmat Shipping System that is currently in use to keep in compliance with the current DOT Hazmat regulations. Created an organized email group system for tracking service, productivity and work allocation within the department. Acted as a central communication center for shipping needs of the company including the 29 branch locations. Played a major role in instituting the shipping processes during a transition to a new system. Ensured my employees felt like they were a part of a team that had purpose. Led my team to exceed the needs and requests of internal and external customers. Contributed to inventory and warehouse implementations that ultimately increased productivity and customer satisfaction.

### Customer Service Agent/Lead: August 2012 –April 2015

### BR Funsten & Tom Duffy Co. - Manteca, CA

- Provided excellent customer service to each and every customer. Developed strong relationships and great rapport with our customers. Worked in a fast-paced environment required strong organizational skills, attention to detail and an ability to handle high stress situations calmly. Processed customer orders, back orders, direct orders and purchase orders.

## Education

BSBM to be complete 2023

| | | |
|---|---|---|
| High School Diploma | 2009 | 3.75GPA |
| Hazmat Certified | 2016 | |

## Skills

- Intermediate-to-advanced skill level in all Microsoft applications
- Firm understanding of lean manufacturing and 6 Sigma principles
- Able to manage inventory, shipments and warehouse processes effectively
- Ability to create and maintain systems to accurately track metrics and provide correct analysis on individual and team results.

775-430-1624 • caseybrown082021@gmail.com

# Casey Brown

## References

Gary Burkert – Warehouse Manager at BR Funsten Co.
(209) [redacted] • gburkert@brfunsten.com

Stacy Funkhouser – Customer Service Manager at BR Funsten Co.
(209) [redacted] • sfunkhouser@brfunsten.com

Craig Whittles – Operations Manager at BR Funsten Co.
(707) [redacted] • cwhittles@brfunsten.com

Trevour Brown – Lead Engineer at H&T
(805) [redacted] • [redacted]

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of MDEG: Reliable HealthCare Logistics, LLC — MDEG License # (if applicable): _____

Physical Address: 1175 Trademark Drive # 100

City: Reno — State: NV — Zip: 89521

Mailing Address (if different from physical address): 951 Clint Moore Road, Suite A

City: Boca Raton — State: FL — Zip: 33487

Telephone: 561-998-3885 — Website: https://www.reliablehealthcarelogistics.com/

Licensing Company Email: sugarlandlicense@rhcl3pl.com

**Section 2: Personal Information**

First: Casey — Middle: Christine — Last: Brown

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted] Homann Way

City: Carson City — State: NV — Zip: 89703

Telephone: [redacted] — Email: cbrown@rhcl3pl.com

Are you a citizen of the United States? ☒ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✔ |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Sierra High School | | 08/05 - 05/09 | |
| **Address** | **City** | **State** | **Zip** |
| | Carson City | | |
| **Diploma/Degree obtained, if any** | | | |
| High School Diploma | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |
| **School Name** | | **From - To (MM/YY – MM/YY)** | |
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |
| **School Name** | | **From - To (MM/YY – MM/YY** | |
| | | | |
| **Address** | **City** | **State** | **Zip** |
| | | | |
| **Diploma/Degree obtained, if any** | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 06/22 - Present | [redacted]Homann Way | Carson City | NV | 89703 |
| 03/20 - 06/22 | [redacted]Pintail Drive | Carson City | NV | 89701 |
| 06/18 - 03/20 | [redacted] Overland Loop | Dayton | NV | 89430 |
| 01/18 - 06/18 | [redacted]Arizona Circle | Carson City | NV | 89701 |
| 11/17 - 1/18 | [redacted]Compass Lane | Manteca | CA | 95337 |
| 11/16 - 11/17 | [redacted]N Locust Ave | Ripon | CA | 95366 |
| 1/14 - 11/16 | [redacted]W Ripon Rd | Ripon | CA | 95366 |
| 10/12 - 01/14 | [redacted]San Juan St | Manteca | CA | 95336 |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
| From - To (MM/YY – MM/YY) | Address | City | State | Zip |

**Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Reliable HealthCare Logistics, LLC | | | 08/2022 - Present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 1175 Trademark Drive, Suite 101 | | Reno | NV | 89521 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 775-376-1121 Ext 451 | Facility Manager | | 1,560.00 | |
| **Description of Duties** | | | | |
| See Resume | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Woodfield Distribution, LLC | | | 07/2019 - 08/2022 | |
| **Business Address** | | **City** | **State** | **Zip** |
| 1175 Trademark Drive, Suite 101 | | Reno | NV | 89521 |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| 775-376-1121 Ext 451 | Logistics Manager | | 1,733.33 | |
| **Description of Duties** | | | | |
| See Resume | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | **Number of Employed Hours** | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

Continue on next page if additional space is needed.

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

| Business Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | Number of Employed Hours | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state? | | ✓ |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline. | | ✓ |

**Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # _____ **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Original Signature (electronic, copies or stamps not accepted)

6/2/2023
Date

I, Casey Brown, certify that as the MDEG Administrator for

Reliable HealthCare Logistics, LLC,

that I (initial that you have read and meet the following requirements):

1. C.B Have a high school diploma or its equivalent;
2. C.B Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. C.B Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. C.B Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Casey Brown

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/2/2023

Date

| Board Use Only | Date Received: |
|---|---|

PHILADELPHIA
INSURANCE COMPANIES

Philadelphia Indemnity Insurance Company
One Bala Plaza, Ste. 100
Bala Cynwyd, PA 19004

# BOND RIDER

**Bond No:** PB11499808261

**Principal:** RELIABLE HEALTHCARE LOGISTICS, LLC

**Obligee:** the State of Nevada and the Nevada State Board of Pharmacy

**Surety:** Philadelphia Indemnity Insurance Company

**Effective:** March 30, 2023

**It is agreed that:** Principal's Address is Changing:

From: 1113 Gillingham Lane, Suite A, Sugar Land, TX 77478

To: 1175 Trademark Dr., Suite 101, Reno, NV 89521

**Nothing herein contained shall be held to vary, waive, alter, or extend any of the terms, conditions, agreements or warranties of the above mentioned bond, other than stated as above. Provided, however, that the liability of the company under the attached bond as changed by this order shall not be cumulative.**

**Signed this** 31st **day of** March **. 20** 23 **.**

**Principal:**

**By:** _____
**Principal Signature**

**Philadelphia Indemnity Insurance Company**

**By:** _____
**John D. Weisbrot, Attorney in Fact**

[illegible]

[illegible]

[illegible]

**PHILADELPHIA INDEMNITY INSURANCE COMPANY**
One Bala Plaza, Suite 100
Bala Cynwyd, PA 19004-0950

**Power of Attorney**

KNOW ALL PERSONS BY THESE PRESENTS: That **PHILADELPHIA INDEMNITY INSURANCE COMPANY** (the Company), a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, does hereby constitute and appoint JOHN D. WEISBROT, MELISSA L. MCDADE OR STEVEN M. VARGA its true and lawful Attorney-in-fact with full authority to execute on its behalf bonds, undertakings, recognizances and other contracts of indemnity and writings obligatory in the nature thereof, issued in the course of its business and to bind the Company thereby, in an amount not to exceed $50,000,000.

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of PHILADELPHIA INDEMNITY INSURANCE COMPANY on the 14th of November, 2016.

**RESOLVED:** That the Board of Directors hereby authorizes the President or any Vice President of the Company: (1) Appoint Attorney(s) in Fact and authorize the Attorney(s) in Fact to execute on behalf of the Company bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof and to attach the seal of the Company thereto; and (2) to remove, at any time, any such Attorney-in-Fact and revoke the authority given. And, be it

**FURTHER RESOLVED:** That the signatures of such officers and the seal of the Company may be affixed to any such Power of Attorney or certificate relating thereto by facsimile, and any such Power of Attorney so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking to which it is attached.

IN TESTIMONY WHEREOF, PHILADELPHIA INDEMNITY INSURANCE COMPANY HAS CAUSED THIS INSTRUMENT TO BE SIGNED AND ITS CORPORATE SEALTO BE AFFIXED BY ITS AUTHORIZED OFFICE THIS 5TH DAY OF MARCH, 2021.

(Seal)

John Glomb, President & CEO
Philadelphia Indemnity Insurance Company

On this 5th day of March, 2021 before me came the individual who executed the preceding instrument, to me personally known, and being by me duly sworn said that he is the therein described and authorized officer of the **PHILADELPHIA INDEMNITY INSURANCE COMPANY**; that the seal affixed to said instrument is the Corporate seal of said Company; that the said Corporate Seal and his signature were duly affixed.

Commonwealth of Pennsylvania - Notary Seal
Vanessa Mckenzie, Notary Public
Montgomery County
My commission expires November 3, 2024
Commission number 1366394
Member, Pennsylvania Association of Notaries

Notary Public: Vanessa McKenzie

residing at: Bala Cynwyd, PA

My commission expires: November 3, 2024

I, Edward Sayago, Corporate Secretary of PHILADELPHIA INDEMNITY INSURANCE COMPANY, do hereby certify that the foregoing resolution of the Board of Directors and the Power of Attorney issued pursuant thereto on the 5th day March, 2021 are true and correct and are still in full force and effect. I do further certify that John Glomb, who executed the Power of Attorney as President, was on the date of execution of the attached Power of Attorney the duly elected President of PHILADELPHIA INDEMNITY INSURANCE COMPANY.

In Testimony Whereof I have subscribed my name and affixed the facsimile seal of each Company this 31st day of March 20 23

Edward Sayago, Corporate Secretary
**PHILADELPHIA INDEMNITY INSURANCE COMPANY**



DocuSign Envelope ID: 80E6D0FD-F56E-4105-9012-5C726351A08C

# PHILADELPHIA INDEMNITY INSURANCE COMPANY

## Statutory Statements of Admitted Assets, Liabilities and Capital and Surplus
(In thousands, except par value and share amounts)

| Admitted Assets | As of December 31, 2021 | 2020 |
|---|---|---|
| Bonds (fair value $8,447,694 and $8,041,263) | $ 8,102,442 | $ 7,601,946 |
| Preferred stocks (fair value $19,262 and $16,537) | 19,262 | 15,673 |
| Common stocks (cost $44,923 and $52,609) | 43,194 | 43,373 |
| Mortgage loans | 957,986 | 821,250 |
| Real estate | 29,408 | 29,973 |
| Other invested assets (cost $194,229 and $203,028) | 218,926 | 215,589 |
| Receivables for securities sold | 152 | 943 |
| Cash, cash equivalents and short-term investments | 128,587 | 34,279 |
| Cash and invested assets | 9,499,957 | 8,763,026 |
| Premiums receivable, agents' balances and other receivables | 914,676 | 908,602 |
| Reinsurance recoverable on paid loss and loss adjustment expenses | 45,200 | 38,737 |
| Accrued investment income | 74,000 | 74,070 |
| Receivable from affiliates | 5,171 | 7,586 |
| Federal income taxes receivable | 8,144 | - |
| Net deferred tax assets | 141,943 | 138,129 |
| Other assets | 9,953 | 4,997 |
| Total admitted assets | $ 10,699,044 | $ 9,935,147 |

| Liabilities and Capital and Surplus | | |
|---|---|---|
| Liabilities: | | |
| Unpaid loss and loss adjustment expenses | $ 5,436,808 | $ 5,218,304 |
| Unearned premiums | 1,658,339 | 1,582,116 |
| Reinsurance payable on paid loss and loss adjustment expenses | 35,820 | 30,398 |
| Ceded reinsurance premiums payable | 130,474 | 108,936 |
| Commissions payable, contingent commissions and other similar charges | 228,628 | 214,389 |
| Federal income taxes payable | - | 8,480 |
| Funds held | 77,317 | 77,256 |
| Payable to affiliates | 19,465 | 18,486 |
| Provision for reinsurance | 471 | 87 |
| Payable for securities purchased | 19,045 | 17,820 |
| Accrued expenses and other liabilities | 47,213 | 32,170 |
| Total liabilities | 7,653,580 | 7,308,442 |
| Capital: | | |
| Common stock, par value of $10 per share; 1,000,000 shares authorized, 450,000 shares issued and outstanding | 4,500 | 4,500 |
| Surplus: | | |
| Gross paid-in and contributed surplus | 386,071 | 386,071 |
| Unassigned surplus | 2,654,893 | 2,236,134 |
| Total surplus | 3,040,964 | 2,622,205 |
| Total capital and surplus | 3,045,464 | 2,626,705 |
| Total liabilities and capital and surplus | $ 10,699,044 | $ 9,935,147 |

The undersigned, being duly sworn, says: That she is the Executive Vice President and Chief Financial Officer of Philadelphia Indemnity Insurance Company; that said Company is a corporation duly organized in the state of Pennsylvania, and licensed and engaged in the State of Pennsylvania and has duly complied with all the requirements of the laws of the said State applicable of the said Company and is duly qualified to act as Surety under such laws; that said Company has also complied with and is duly qualified to act as Surety under the Act of Congress. And that to the best of her knowledge and belief the above statement is a full, true and correct statement of

Attest:

DocuSigned by:
Karen Gilmer-Pauciello
Karen Gilmer-Pauciello, EVP & CFO

Sworn to before me this 2nd day of June 2022.

Kimberly Kessleski, Notary

Commonwealth of Pennsylvania - Notary Seal
Kimberly A. Kessleski, Notary Public
Montgomery County
My commission expires December 18, 2024
Commission number 1245769
Member, Pennsylvania Association of Notaries

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## Personal History Application

Rev (05/13/2022)

**Section 1: Pharmacy/ MDEG/Wholesaler Information**

Name of Pharmacy/MDEG/Wholesaler: Reliable Healthcare Logistics, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable):

Physical Address: 1175 Trademark Drive, Suite 101

City: Reno State: NV Zip: 89521

Mailing Address (if different from physical address): 951 Clint Moore Road, Suite A

City: Boca Raton State: FL Zip: 33487

Telephone: 561-998-3885 Ext. 216 Website: www.reliablehealthcarelogistics.com

Licensing Company Email: 1175license@reliablehealthcarelogistics.com

**Section 2: Personal Information**

First: Tyler Middle: Christopher Last: Kattawar

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Courts Meadow Court

City: Collierville State: TN Zip: 38017

Telephone: [redacted] Email: tkattawar@reliablehealthcarelogistics.com

Are you a citizen of the United States? ■ Yes ☐ No

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

**Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| University of Memphis | | 08/2009-05/2012 | |
| Address | City | State | Zip |
| 3720 Alumni Avenue | Memphis | TN | 38152 |
| Diploma/Degree obtained, if any | | | |
| BBA in Logistics/Supply Chain Management | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| Houston High School | | 08/2003-05/2007 | |
| Address | City | State | Zip |
| 9755 Wolf River Blvd | Collierville | TN | 38017 |
| Diploma/Degree obtained, if any | | | |
| High School Dipoloma | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

| School Name | | From - To (MM/YY – MM/YY | |
|---|---|---|---|
| | | | |
| Address | City | State | Zip |
| | | | |
| Diploma/Degree obtained, if any | | | |
| | | | |

**Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)**

| From - To (MM/YY – MM/YY) | Address | City | State | Zip |
|---|---|---|---|---|
| 06/2020-Present | [redacted] Courts Meadow Court | Collierville | TN | 38017 |
| 12/2011-06/2020 | [redacted] Grays Lake Cove | Cordova | TN | 38018 |
| | | | | |
| | | | | |
| | | | | |
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| | | | | |
| | | | | |

**Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.**

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| KPower Global Logistics, LLC | | | 09/2016-Present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 4105 Mendenhall Road | | Memphis | TN | 38118 |
| **Phone** | **Title** | | | |
| 901-261-0944 | Chief Operating Officer | | | |
| **Description of Duties** | | | | |
| Oversight of day to day operations. | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| Phoenix Assurance, LLC | | | 05/2019-Present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 4750 Pleasant Hill Road | | Memphis | TN | 38115 |
| **Phone** | **Title** | | | |
| 901-368-8940 | Chief Operating Officer | | | |
| **Description of Duties** | | | | |
| Oversight of day to day operations. | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| KattRx Pharmacy, LLC | | | 1/2022-Present | |
| **Business Address** | | **City** | **State** | **Zip** |
| 4750 Pleasant Hill Road | | Memphis | TN | 38115 |
| **Phone** | **Title** | | | |
| 901-368-8968 | Chief Operating Officer | | | |
| **Description of Duties** | | | | |
| Oversight of day to day operations. | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

| Business Name | | | From - To (MM/YY – MM/YY) | |
|---|---|---|---|---|
| | | | | |
| **Business Address** | | **City** | **State** | **Zip** |
| | | | | |
| **Phone** | **Title** | | | |
| | | | | |
| **Description of Duties** | | | | |
| | | | | |

Continue on next page if additional space is needed.

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

| Business Name | | | From - To (MM/YY – MM/YY) |
|---|---|---|---|
| Business Address | City | State | Zip |
| Phone | Title | | |
| Description of Duties | | | |

Make copies of this page OR use a separate piece of paper if additional space is needed.

| Section 8: Arrests, Detentions, Litigations, Arbitrations. | Yes | No |
|---|---|---|
| 1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.) | | ✓ |
| 2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? | | ✓ |
| 3. Have you ever had a civil or criminal record expunged or sealed by a court order? | | ✓ |
| 4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.) | | ✓ |
| 5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy? | | ✓ |
| 6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)? | | ✓ |
| 7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity? | | ✓ |
| 8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license. | | ✓ |
| 9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer). | | ✓ |
| 10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # _____. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| Reason/Charge | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| Name of Business/Industry/Entity | | | | |

**Provide explanation below:**

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Tyler Kattawar

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/2/2023

Date

---

**Please have this section completed in the presence of a Notary Public.**

State of TENNESSE, ss. County of SHELBY

I, Tyler Kattawar, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

**Original Signature**

2/2/2023

**Date**

Subscribed and Sworn to before me this 2nd day of FEBRUARY 2023

**Notary Public Signature**

ROBERT OSBORNE
STATE OF TENNESSEE NOTARY PUBLIC
COUNTY OF SHELBY

**(Seal)**

# Tyler Kattawar

[redacted]Courts Meadow Cove, Collierville, TN 38017 | [redacted]

## Overview

As a C-level executive and operations leader, I bring a record of success and expertise in delivering strategic initiatives for the companies I have worked with. I excel at simplifying cumbersome and overly complex business processes that deliver a bottom-line impact, creating a clear and engaging vision for change, and building cross-functional partnerships that enable long-term growth. Beyond results, I have a reputation for quickly fixing problems, regardless of the internal or market challenge—a key in my ability to consistently redefine what is possible for the organizations I represent.

## Education

### BACHELOR OF BUSINESS ADMINISTRATION | MAY 2012 | UNIVERSITY OF MEMPHIS

- Major: Supply Chain/Logistics

## Skills & Abilities

### MANAGEMENT

- Supply Chain Operations, Third-Party Logistics, Healthcare Operations, Consumer Products, Executive Leadership, Mergers & Acquisitions, Process Improvement, Solutions Modeling and Innovation, WMS/ERP/IT Integrations, KPI Development and Management, Retail & E-Commerce Fulfillment

### SALES

- Onboarded over 50+ new accounts, lead sales meetings and incentive programs, account manager for unique, high-profile clients to ensure proper attention to detail

### LEADERSHIP

- Vice President of SCMSA (Supply Chain Management Student Association)
- Managing Partner of Multiple Companies
  - KPower Global Logistics, LLC.
  - Power Express, Inc.
  - Traffic Consultants, Inc.
  - Phoenix Assurance, LLC.

## Experience

### CHIEF OPERATION OFFICER | PHOENIX ASSURANCE, LLC | OCTOBER 2018 - PRESENT

- Manage day-to-day operations and big picture growth opportunities
- Prospect new clients and determine best strategy for optimized profits
- Provide support for regulatory and license requirements for all facilities
- Develop operational standards to improve efficiencies
- Implement technology systems (WMS, ERP, EDI, TMS) to continue improving throughput
  - Synapse, PCS, Royal4, Liaison, Office365

**CHIEF OPERATING OFFICER | KPOWER GLOBAL LOGISTICS | MAY 2018 - PRESENT**

- Manage day-to-day operations and big picture growth opportunities
- Oversee 50+ direct report personnel
- Prospect new clients and determine best strategy for optimized profits
- AR/AP oversight with the accounting team directly reporting
- Develop operational standards to improve efficiencies
- Implement technology systems (WMS, ERP, EDI, TMS) to continue improving throughput
  - Synapse, PCS, Royal4, Liaison, Office365

**EXECUTIVE VICE PRESIDENT - OPERATIONS | KPOWER GLOBAL LOGISTICS | SEPTEMBER 2015 – MAY 2018**

- Onboard all new customers
- Personally involved with new business startups in 10+ different states
- Refocused team members to understand profitability and how to achieve next level results
- Developed cross functional team members to broaden the skillset across company and eliminate possible failures

**EAST COAST OPERATIONS MANAGER | LOGISTICS & DISTRIBUTION SERVICES | MARCH 2013 – SEPTEMBER 2015**

- Operational Control of 75+ Tractors and 125+ Trailers (Refrigerated and Dry)
- Started Brokerage Division for East Coast Branch
- Management and Financial oversight of 10 associates
- Maintained ELOGS and IFTA Fuel Tax for all tractors and drivers
- Onboarded and vetted new carriers through FMCSA and internal safety systems

**OPERATIONS/IT MANAGER | EAGLE WORLDWIDE | JANUARY 2010 – MARCH 2013**

- Operational control of 50+ Tractors and 100+ Trailers (Refrigerated, Flatbed, and Dry)
- Transitioned from enterprise version of Microsoft Office to Office365 with complete company deployment
- Upgraded all software from non-supported versions to more robust, advanced versions
  - PCS
  - PCMiler
  - Kaspersky
- Accommodated transition to new facility which included tractors, trailers, personnel, assets, documents and all other material over a 2-week time frame
- Prepared M&A documents, financials, background information, and overall analysis for potential transactions

**REFERENCES**

Charles Mathews
Logistics & Distribution Services
775-691-1858

Tim Purselley
ABS Marketing
901-240-1160

Barry Bernard
Ohio Intermodal Services
901-634-8072

IRS.gov

EIN Assistant

... 5. EIN Confirmation

**Congratulations! Your EIN has been successfully assigned.**

EIN Assigned: 85-1175079

Legal Name: RELIABLE HEALTHCARE LOGISTICS LLC

**IMPORTANT:**

**Save and/or print this page and the confirmation letter below for your permanent records.**

The confirmation letter below is your official IRS notice and contains important information regarding your EIN.

CLICK HERE for Your EIN Confirmation Letter — Help with saving and printing your letter

Once you have saved or printed your letter, click "Continue" to get additional information about using your new EIN. Continue >>

Help Topics

- What if I do not have access to a printer at this time?
- Can I access this letter at a later date?

IRS DEPARTMENT OF THE TREASURY
INTERNAL REVENUE SERVICE
CINCINNATI OH 45999-0023

Date of this notice: 03-11-2022

Employer Identification Number:
88-1175079

Form: SS-4

Number of this notice: CP 575 A

RELIABLE HEALTHCARE LOGISTICS LLC
TYLER KATTAWAR MBR
4750 PLEASANT HILL RD STE 3
MEMPHIS, TN 38118

For assistance you may call us at:
1-800-829-4933

IF YOU WRITE, ATTACH THE
STUB AT THE END OF THIS NOTICE.

## WE ASSIGNED YOU AN EMPLOYER IDENTIFICATION NUMBER

Thank you for applying for an Employer Identification Number (EIN). We assigned you EIN 88-1175079. This EIN will identify you, your business accounts, tax returns, and documents, even if you have no employees. Please keep this notice in your permanent records.

Taxpayers request an EIN for their business. Some taxpayers receive CP575 notices when another person has stolen their identity and are opening a business using their information. If you did **not** apply for this EIN, please contact us at the phone number or address listed on the top of this notice.

When filing tax documents, making payments, or replying to any related correspondence, it is very important that you use your EIN and complete name and address exactly as shown above. Any variation may cause a delay in processing, result in incorrect information in your account, or even cause you to be assigned more than one EIN. If the information is not correct as shown above, please make the correction using the attached tear-off stub and return it to us.

Based on the information received from you or your representative, you must file the following forms by the dates shown.

| | |
|---|---|
| Form 941 | 07/31/2022 |
| Form 940 | 01/31/2023 |
| Form 1065 | 03/15/2023 |

If you have questions about the forms or the due dates shown, you can call us at the phone number or write to us at the address shown at the top of this notice. If you need help in determining your annual accounting period (tax year), see Publication 538, *Accounting Periods and Methods*.

We assigned you a tax classification (corporation, partnership, etc.) based on information obtained from you or your representative. It is not a legal determination of your tax classification, and is not binding on the IRS. If you want a legal determination of your tax classification, you may request a private letter ruling from the IRS under the guidelines in Revenue Procedure 2020-1, 2020-1 I.R.B. 1 (or superseding Revenue Procedure for the year at issue). Note: Certain tax classification elections can be requested by filing Form 8832, *Entity Classification Election*. See Form 8832 and its instructions for additional information.

IMPORTANT INFORMATION FOR S CORPORATION ELECTION:
If you intend to elect to file your return as a small business corporation, an election to file a Form 1120-S, U.S. Income Tax Return for an S Corporation, must be made within certain timeframes and the corporation must meet certain tests. All of this information is included in the instructions for Form 2553, Election by a Small Business Corporation.

(IRS USE ONLY) 575A 03-11-2022 RELI B 9999999999 SS-4

A limited liability company (LLC) may file Form 8832, *Entity Classification Election*, and elect to be classified as an association taxable as a corporation. If the LLC is eligible to be treated as a corporation that meets certain tests and it will be electing S corporation status, it must timely file Form 2553, *Election by a Small Business Corporation*. The LLC will be treated as a corporation as of the effective date of the S corporation election and does not need to file Form 8832.

If you are required to deposit for employment taxes (Forms 941, 943, 940, 944, 945, CT-1, or 1042), excise taxes (Form 720), or income taxes (Form 1120), you will receive a Welcome Package shortly, which includes instructions for making your deposits electronically through the Electronic Federal Tax Payment System (EFTPS). A Personal Identification Number (PIN) for EFTPS will also be sent to you under separate cover. Please activate the PIN once you receive it, even if you have requested the services of a tax professional or representative. For more information about EFTPS, refer to Publication 966, *Electronic Choices to Pay All Your Federal Taxes*. If you need to make a deposit immediately, you will need to make arrangements with your Financial Institution to complete a wire transfer.

The IRS is committed to helping all taxpayers comply with their tax filing obligations. If you need help completing your returns or meeting your tax obligations, Authorized e-file Providers, such as Reporting Agents or other payroll service providers, are available to assist you. Visit www.irs.gov/mefbusproviders for a list of companies that offer IRS e-file for business products and services.

**IMPORTANT REMINDERS:**

* Keep a copy of this notice in your permanent records. This notice is issued only one time and the IRS will not be able to generate a duplicate copy for you. You may give a copy of this document to anyone asking for proof of your EIN.
* Use this EIN and your name exactly as they appear at the top of this notice on all your federal tax forms.
* Refer to this EIN on your tax-related correspondence and documents.
* Provide future officers of your organization with a copy of this notice.

Your name control associated with this EIN is RELI. You will need to provide this information along with your EIN, if you file your returns electronically.

Safeguard your EIN by referring to Publication 4557, Safeguarding Taxpayer Data: A Guide for Your Business.

You can get any of the forms or publications mentioned in this letter by visiting our website at www.irs.gov/forms-pubs or by calling 800-TAX-FORM (800-829-3676).

If you have questions about your EIN, you can contact us at the phone number or address listed at the top of this notice. If you write, please tear off the stub at the bottom of this notice and include it with your letter.

Thank you for your cooperation.

(IRS USE ONLY) 575A 03-11-2022 RELI B 9999999999 SS-4

Keep this part for your records. CP 575 A (Rev. 7-2007)

---

Return this part with any correspondence so we may identify your account. Please correct any errors in your name or address.

CP 575 A

9999999999

Your Telephone Number
( ) -
_____

Best Time to Call
_____

DATE OF THIS NOTICE: 03-11-2022
EMPLOYER IDENTIFICATION NUMBER: 88-1175079
FORM: SS-4 NOBOD

INTERNAL REVENUE SERVICE
CINCINNATI OH 45999-0023

RELIABLE HEALTHCARE LOGISTICS LLC
TYLER KATTAWAR MBR
4750 PLEASANT HILL RD STE 3
MEMPHIS, TN 38118

Form **SS-4** (Rev. December 2019)
Department of the Treasury Internal Revenue Service

# Application for Employer Identification Number

(For use by employers, corporations, partnerships, trusts, estates, churches, government agencies, Indian tribal entities, certain individuals, and others.)
▶ Go to *www.irs.gov/FormSS4* for instructions and the latest information.
▶ See separate instructions for each line. ▶ Keep a copy for your records.

OMB No. 1545-0003
EIN

Type or print clearly.

1 Legal name of entity (or individual) for whom the EIN is being requested
Reliable HealthCare Logistics, LLC

2 Trade name of business (if different from name on line 1)

3 Executor, administrator, trustee, "care of" name

4a Mailing address (room, apt., suite no. and street, or P.O. box)
4760 Pleasant Hill Road, Suite 3

5a Street address (if different) (Don't enter a P.O. box.)

4b City, state, and ZIP code (if foreign, see instructions)
Memphis, TN 38118

5b City, state, and ZIP code (if foreign, see instructions)

6 County and state where principal business is located
Shelby County, Tennessee

7a Name of responsible party
Tyler Kaltawar

7b SSN, ITIN, or EIN
on file

8a Is this application for a limited liability company (LLC) (or a foreign equivalent)? ☑ Yes ☐ No

8b If 8a is "Yes," enter the number of LLC members ▶ 0

8c If 8a is "Yes," was the LLC organized in the United States? ☑ Yes ☐ No

9a Type of entity (check only one box). Caution: If 8a is "Yes," see the instructions for the correct box to check.
- ☐ Sole proprietor (SSN) _____
- ☑ Partnership
- ☐ Corporation (enter form number to be filed) ▶ _____
- ☐ Personal service corporation
- ☐ Church or church-controlled organization
- ☐ Other nonprofit organization (specify) ▶ _____
- ☐ Other (specify) ▶
- ☐ Estate (SSN of decedent) _____
- ☐ Plan administrator (TIN) _____
- ☐ Trust (TIN of grantor) _____
- ☐ Military/National Guard ☐ State/local government
- ☐ Farmers' cooperative ☐ Federal government
- ☐ REMIC ☐ Indian tribal governments/enterprises

Group Exemption Number (GEN) if any ▶

9b If a corporation, name the state or foreign country (if applicable) where incorporated — State: _____ Foreign country: _____

10 Reason for applying (check only one box)
- ☑ Started new business (specify type) ▶ _____
- ☐ Hired employees (Check the box and see line 13.)
- ☐ Compliance with IRS withholding regulations
- ☐ Other (specify) ▶
- ☐ Banking purpose (specify purpose) ▶ _____
- ☐ Changed type of organization (specify new type) ▶ _____
- ☐ Purchased going business
- ☐ Created a trust (specify type) ▶ _____
- ☐ Created a pension plan (specify type) ▶ _____

11 Date business started or acquired (month, day, year). See instructions.
March 4, 2022

12 Closing month of accounting year December

13 Highest number of employees expected in the next 12 months (enter -0- if none). If no employees expected, skip line 14.

| Agricultural | Household | Other |
|---|---|---|
| 0 | 0 | 106 |

14 If you expect your employment tax liability to be $1,000 or less in a full calendar year and want to file Form 944 annually instead of Forms 941 quarterly, check here. (Your employment tax liability generally will be $1,000 or less if you expect to pay $5,000 or less in total wages.) If you don't check this box, you must file Form 941 for every quarter. ☐

15 First date wages or annuities were paid (month, day, year). Note: If applicant is a withholding agent, enter date income will first be paid to nonresident alien (month, day, year) ▶ 4/1/2022

16 Check one box that best describes the principal activity of your business.
☐ Construction ☐ Rental & leasing ☐ Transportation & warehousing ☑ Health care & social assistance ☐ Wholesale-agent/broker ☐ Wholesale-other ☐ Retail
☐ Real estate ☐ Manufacturing ☐ Finance & insurance ☐ Other (specify) ▶

17 Indicate principal line of merchandise sold, specific construction work done, products produced, or services provided.

18 Has the applicant entity shown on line 1 ever applied for and received an EIN? ☐ Yes ☑ No
If "Yes," write previous EIN here ▶

**Third Party Designee**

Complete this section only if you want to authorize the named individual to receive the entity's EIN and answer questions about the completion of this form.

Designee's name: Rebecca Ware
Designee's telephone number (include area code): 615-259-9979
Address and ZIP code: 150 Third Avenue South, Suite 2800, Nashville, TN 37201
Designee's fax number (include area code):

Under penalties of perjury, I declare that I have examined this application, and to the best of my knowledge and belief, it is true, correct, and complete.
Applicant's telephone number (include area code): 901-803-7839
Name and title (type or print clearly) ▶ Tyler Kaltawar
Applicant's fax number (include area code):
Signature ▶ [signature] Date ▶ 3/10/2022

## Do I Need an EIN?

File Form SS-4 if the applicant entity doesn't already have an EIN but is required to show an EIN on any return, statement, or other document.[1] See also the separate instructions for each line on Form SS-4.

| IF the applicant... | AND... | THEN... |
|---|---|---|
| started a new business | doesn't currently have (nor expect to have) employees | complete lines 1, 2, 4a–8a, 8b–c (if applicable), 9a, 9b (if applicable), and 10–14 and 16–18. |
| hired (or will hire) employees, including household employees | doesn't already have an EIN | complete lines 1, 2, 4a–6, 7a–b, 8a, 8b–c (if applicable), 9a, 9b (if applicable), 10–18. |
| opened a bank account | needs an EIN for banking purposes only | complete lines 1–5b, 7a–b, 8a, 8b–c (if applicable), 9a, 9b (if applicable), 10, and 18. |
| changed type of organization | either the legal character of the organization or its ownership changed (for example, you incorporate a sole proprietorship or form a partnership)[2] | complete lines 1–18 (as applicable). |
| purchased a going business[3] | doesn't already have an EIN | complete lines 1–18 (as applicable). |
| created a trust | the trust is other than a grantor trust or an IRA trust[4] | complete lines 1–18 (as applicable). |
| created a pension plan as a plan administrator[5] | needs an EIN for reporting purposes | complete lines 1, 2, 4a–5b, 7a–b, 9a, 10, and 18. |
| is a foreign person needing an EIN to comply with IRS withholding regulations | needs an EIN to complete a Form W-8 (other than Form W-8ECI), avoid withholding on portfolio assets, or claim tax treaty benefits[6] | complete lines 1–5b, 7a–b (SSN or ITIN as applicable), 8a, 8b–c (if applicable), 9a, 9b (if applicable), 10, and 18. |
| is administering an estate | needs an EIN to report estate income on Form 1041 | complete lines 1–7b, 9a, 10–12, 13–17 (if applicable), and 18. |
| is a withholding agent for taxes on nonwage income paid to an alien (that is, individual, corporation, or partnership, etc.) | is an agent, broker, fiduciary, manager, tenant, or spouse who is required to file Form 1042, Annual Withholding Tax Return for U.S. Source Income of Foreign Persons | complete lines 1, 2, 3 (if applicable), 4a–5b, 7a–b, 8a, 8b–c (if applicable), 9a, 9b (if applicable), 10, and 18. |
| is a state or local agency | serves as a tax reporting agent for public assistance recipients under Rev. Proc. 80-4, 1980-1 C.B. 581[7] | complete lines 1, 2, 4a–5b, 7a–b, 9a, 10, and 18. |
| is a single-member LLC (or similar single-member entity) | needs an EIN to file Form 8832, Entity Classification Election, for filing employment tax returns and excise tax returns, or for state reporting purposes[8], or is a foreign-owned U.S. disregarded entity and needs an EIN to file Form 5472, Information Return of a 25% Foreign-Owned U.S. Corporation or a Foreign Corporation Engaged in a U.S. Trade or Business | complete lines 1–18 (as applicable). |
| is an S corporation | needs an EIN to file Form 2553, Election by a Small Business Corporation[9] | complete lines 1–18 (as applicable). |

[1] For example, a sole proprietorship or self-employed farmer who establishes a qualified retirement plan, or is required to file excise, employment, alcohol, tobacco, or firearms returns, must have an EIN. A partnership, corporation, REMIC (real estate mortgage investment conduit), nonprofit organization (church, club, etc.), or farmers' cooperative must use an EIN for any tax-related purpose even if the entity doesn't have employees.

[2] However, don't apply for a new EIN if the existing entity only (a) changed its business name, (b) elected on Form 8832 to change the way it is taxed (or is covered by the default rules), or (c) terminated its partnership status because at least 50% of the total interests in partnership capital and profits were sold or exchanged within a 12-month period. The EIN of the terminated partnership should continue to be used. See Regulations section 301.6109-1(d)(2)(i).

[3] Don't use the EIN of the prior business unless you became the "owner" of a corporation by acquiring its stock.

[4] However, grantor trusts that don't file using Optional Method 1 and IRA trusts that are required to file Form 990-T, Exempt Organization Business Income Tax Return, must have an EIN. For more information on grantor trusts, see the instructions for Form 1041.

[5] A plan administrator is the person or group of persons specified as the administrator by the instrument under which the plan is operated.

[6] Entities applying to be a Qualified Intermediary (QI) need a QI-EIN even if they already have an EIN. See Rev. Proc. 2000-12.

[7] See also *Household employer agent* in the Instructions. Note: State or local agencies may need an EIN for other reasons, for example, hired employees.

[8] See *Disregarded entities* in the Instructions for details on completing Form SS-4 for an LLC.

[9] An existing corporation that is electing or revoking S corporation status should use its previously-assigned EIN.

# 13

# 13A

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Pharmaceutical Technician IN TRAINING (PTT) Application

Non-Refundable $50 fee

Rev (03/16/2023)

**Section 1: General Information**

First: Adrianna Middle: Ellis Last: Rivera

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☑ F ☐ X

Mailing Address: [redacted] west tropicana ave Unit [redacted]

City: Las Vegas State: NV Zip: 89103

Telephone: [redacted] Email: [redacted]

**Section 2: Program of Training for Pharmaceutical Technicians (Complete this section ONLY if you are enrolled in a PT school or training program.) NAC 639.258**

Program/School Name: N/A

Address:

City: State: Zip:

Name of Program Director:

Signature of Program Director:

**Section 3: Employment Information**

Pharmacy Name: CVS Pharmacy License #: 20549

Address: 9695 S. Maryland Pkwy

City: Las Vegas State: NV Zip: 89123

| **Section 4: Age and Education Requirements (You do not qualify to be a PT if you answer "NO" in this section.)** | **Yes** | **No** |
|---|---|---|
| 1. Are you 18 years of age or older? | ✓ | |
| 2. Are you a high school graduate or the equivalent? | ✓ | |

High School Name: Abraham Lincoln High School Graduation Date OR Date GED obtained (mm/yy): 6/15/2017

Address: 3201 Ryan Ave

City: Philadelphia State: PA Zip: 19136

| **Section 5: Military Service (NRS 622.120)** | **Yes** | **No** |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 6: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✓ |

| Section 7: Personal and Professional History | | |
|---|---|---|
| **Before answering the questions below, please INITIAL to the right to attest you have read and understand the following:**<br>WARNING<br>You MUST provide truthful and complete responses to the questions on this application. If you omit information or provide false or misleading responses, including any failure to disclose past arrests or expunged convictions, this may be a basis for denial of your application and may result in disciplinary action against any other license or registration you hold from the Board. | Initials<br>AR | |
| | **Yes** | **No** |
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration? | | ✓ |
| 2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state even if the case or charge has been dismissed, sealed, acquitted, or expunged? | ✓ | |
| 3. Have you been the subject of a board citation or administrative action whether completed or pending in <u>any</u> state? | | ✓ |
| 4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state? | | ✓ |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 7 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # 2 . **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| 4/8/22 | 4/8/24 | NV | Las Vegas | Las Vegas |
| **Case #** | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | | |
| C1263820 | City of Las Vegas Municipal Court | | | |
| **Reason/Charge** | | | | |
| First Misdemeanor DUI | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | **Lawsuit/Arbitration/Bankruptcy** | | | |
| City of las Vegas VS Adrianna Rivera | DUI Misdemeanor | | | |
| **Name of Business/Industry/Entity** | | | | |
| N/A | | | | |

**Provide explanation below:** Currently finishing all final payments and courses issued by the state/court for me to ~~to~~ attend. Nov 8 2023 is my return date of court and should be cleared from record.

Original Signature (electronic, copies or stamps not accepted)

6/26/2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I understand that Nevada law requires a registered pharmaceutical technician in training who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Adrianna Rivera

Print Name

Original Signature (electronic, copies or stamps not accepted)

6/26/23

Date

| Board Use Only | Date Received: 6.28.23 | Amount: 50 cc |
|---|---|---|

| Case Number: | Case Name: | Case Type: | Make a Plea / Payment |
|---|---|---|---|
| **C1263820 - Open** | **RIVERA, ADRIANNA** | **Criminal** | |

Case Summary | Other Cases | Documents | Class Schedule | Ledger

## Summary

| Charge Information | Plea | Dispo Date | Disposition |
|---|---|---|---|
| Count# 1 Dui Liquor (57571) on 04/09/2022 (0 Prior MV inc) Points: 0 | Nolo on 04/05/2023 | 05/08/2023 | Found Guilty |

| Court Event | Scheduled For | Result | Reason Continued To This Date | Memo |
|---|---|---|---|---|
| Morning Court/AM Session | 11/08/2023 08:00 AM | | | |
| Arraignment | 04/05/2023 01:00 PM | | | |
| Arraignment | 12/14/2022 01:00 PM | | | |
| Arraignment | 08/08/2022 01:00 PM | | | |
| 05/08/2023 08:15 AM | PreTrial - PA | Completed On 05/08/2023 | | |

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# 13B

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Pharmaceutical Technician IN TRAINING (PTT) Application

**Non-Refundable $50 fee**

Rev (01/18/2023)

4

**Section 1: General Information**

First: BERNICE Middle: M. Last: BENSCOTER

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted] DRIFTWOOD CT.

City: Henderson State: NV Zip: 89015

Telephone: [redacted] Email: [redacted]

**Section 2: Program of Training for Pharmaceutical Technicians (Complete this section ONLY if you are enrolled in a PT school or training program.) NAC 639.258**

Program/School Name: Northwest Career College

Address: 7398 Smoke Ranch Rd

City: Las Vegas State: NV Zip: 89128

Name of Program Director: Samantha Huntsman

Signature of Program Director:

**Section 3: Employment Information**

Pharmacy Name: License #:

Address:

City: State: Zip:

| Section 4: Age and Education Requirements (You do not qualify to be a PT if you answer "NO" in this section.) | Yes | No |
|---|---|---|
| 1. Are you 18 years of age or older? | X | |
| 2. Are you a high school graduate or the equivalent? | X | |

High School Name: Curie High School Graduation Date OR Date GED obtained (mm/yy): 6-86

Address: 4959 S. Archer Ave

City: CHICAGO State: ILL Zip: 60632

| Section 5: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | X |

| Section 6: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | X |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | X |

| Section 7: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration? | X | X |
| 2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state even if the case or charge has been dismissed, sealed, acquitted, or expunged? | X | |
| 3. Have you been the subject of a board citation or administrative action whether completed or pending in <u>any</u> state? | | X |
| 4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state? | | X |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 7 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>**

**This is in response to Question # 2. Provide all the following *<u>where applicable</u>*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| multiple | 2003<br>2009 | NV | Las Vegas | |
| **Case #** 03F05982X<br>09MCH007783 | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| **Reason/Charge** possession & possession of drug paraphernalia | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** misdemeanors | | | **Lawsuit/Arbitration/Bankruptcy** | |
| **Name of Business/Industry/Entity** | | | | |

**Provide explanation below:**

multiple - see attached

* Please see failed drug test attached for question # 1 *

B. Benscoter
Original Signature (electronic, copies or stamps not accepted)

5-9-23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I understand that Nevada law requires a registered pharmaceutical technician in training who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

B Benscoter

Print Name

B Benscoter

Original Signature (electronic, copies or stamps not accepted)

5-09-23

Date

| Board Use Only | Date Received: 6/26/23 | Amount: 50-CK-10957327 |
|---|---|---|

# AMERICAN TOXICOLOGY, INC.

3340 SUNRISE AVE., SUITE 105 LAS VEGAS, NEVADA 89101
Phone:(702)452-2730 Fax:(702)314-1368

| | | | | | |
|---|---|---|---|---|---|
| RE: | Bernice Benscoter | Number: | Date Collected: | 2023-06-08 | Time 4:08 PM |
| SSN: | 0471 | Time from refferal: 24 HOURS | Date Received: | 2023-06-08 | Time |
| Requesting Agency: Northwest Career College | | | Date Reported: | 2023-06-13 | Time 1:02 PM |

## Test(s) Requested

Requested Test: Urine 10

Drugs Tested For:

| Hair - Screening Cutoff | Urine - Screening Cutoff | | Blood - Screening Cutoff | Other - Screening Cutoff |
|---|---|---|---|---|
| | Amphetamines | 500 ng/ml | | |
| | Barbiturates | 300 ng/ml | | |
| | Benzodiazepines | 300 ng/ml | | |
| | Cocaine Metabolites | 150 ng/ml | | |
| | Methadone | 300 ng/ml | | |
| | Opiates | 300 ng/ml | | |
| | Oxycodone | 300 ng/ml | | |
| | Phencyclidine | 25 ng/ml | | |
| | Propoxyphene | 300 ng/ml | | |
| | THC Metabolite | 50 ng/ml | | |

| URINE DRUGS | RESULTS | BLOOD DRUGS | RESULTS |
|---|---|---|---|
| Amphetamine Positive 679ng/ml Methamphetamine Positive 1456ng/ml<br><br>A positive result indicates that the drug was identified at a level greater than its above listed screening cutoff and was confirmed by a second method. | | Not Requested | |

| HAIR DRUGS | RESULTS | OTHER DRUGS | RESULTS |
|---|---|---|---|
| Not Requested | | Not Requested | |

## REPORT NOTATIONS

Phillip Usera, MD, FCAP
Laboratory Director

Nevada State Licensed Medical Laboratory
1440LIC

06/21/2023

To: Nevada State Board of Pharmacy

My name is Bernice "Bonnie" Benscoter and I am currently attending the Pharmacy Technician program at Northwest Career College in Las Vegas, NV. I am writing to provide details about a Misdemeanor I received in 2003. Please see the details below.

- Case No: 03F05982X City, State: Las Vegas, Nevada Arrest Date: 04/05/2003

On April 5th, 2003 it was the first time I was arrested. I had been helping my friends move into a new place and we were hanging up curtains and getting everything ready. It wasn't in the best area, with a high amount of police. My friend and I started getting asked questions by the police consistently, most of which I could not answer, but they thought the Uhaul in the area was suspicious.

I ended up having half a gram of methamphetamine in my pocket at the time, it was given to me by my friend to hold and when the police came up to me asking questions about the moving truck and the people, I did inform them that I had it in my pocket and gave it to them.

I was supposed to go to a baseball game with my sons but instead I was arrested for the first time. It was a scary experience that I was not prepared for, but I made sure that I followed police orders and did not try to hide anything.

I was taken to county jail and released on my own recognizance the same day. I went to court and was given a drug class and a book that I had to complete and they said it would be dropped. I completed everything immediately and focused on moving past the charges.

- Case No: 09MCH007753 City, State: Las Vegas, Nevada Arrest Date: 11/05/2009

On November 5th, 2009, I was spending an evening at my friend's house. I was living there and helping out after his mom passed to assist with the challenges that come up from having someone in your life pass. My friend was having a hard time after his mothers passing and started drinking really heavily as well as other things. People were consistently coming in and out of the house, including those that I didn't know. I was just trying to be a good friend and help and understand that he was going through a rough time after an unexpected death, that I wasn't exactly sure what to do but be there for someone that needed it.

I tried to be a good influence and keep everything as tame as possible, but it is hard when you have people coming in and out, drinking, stealing, breaking things, drug use, everything and my goal was just to keep it as calm as possible and make sure he didn't lose his house or his mind.

On the night of November 5th, the house raided. SWAT brought their giant trucks and believed that my friend was a huge dealer in the area and set off fire crackers in the house and demanded that everyone in the house get out. I was taken out of the house and were forced to sit outside while they destroyed the house looking for anything to incriminate him.

In the end, everyone there was given tickets for possession of drug paraphernalia due to having bongs and test tubes (because it could be made into pipes). In the end, I was not arrested, just given a ticket and

had to pay a fine for $200. This ticket was given to everyone that was in the house. I ended up moving out of the house quickly after that because in the end, as much as I wanted to save my friend, I had to save myself first.

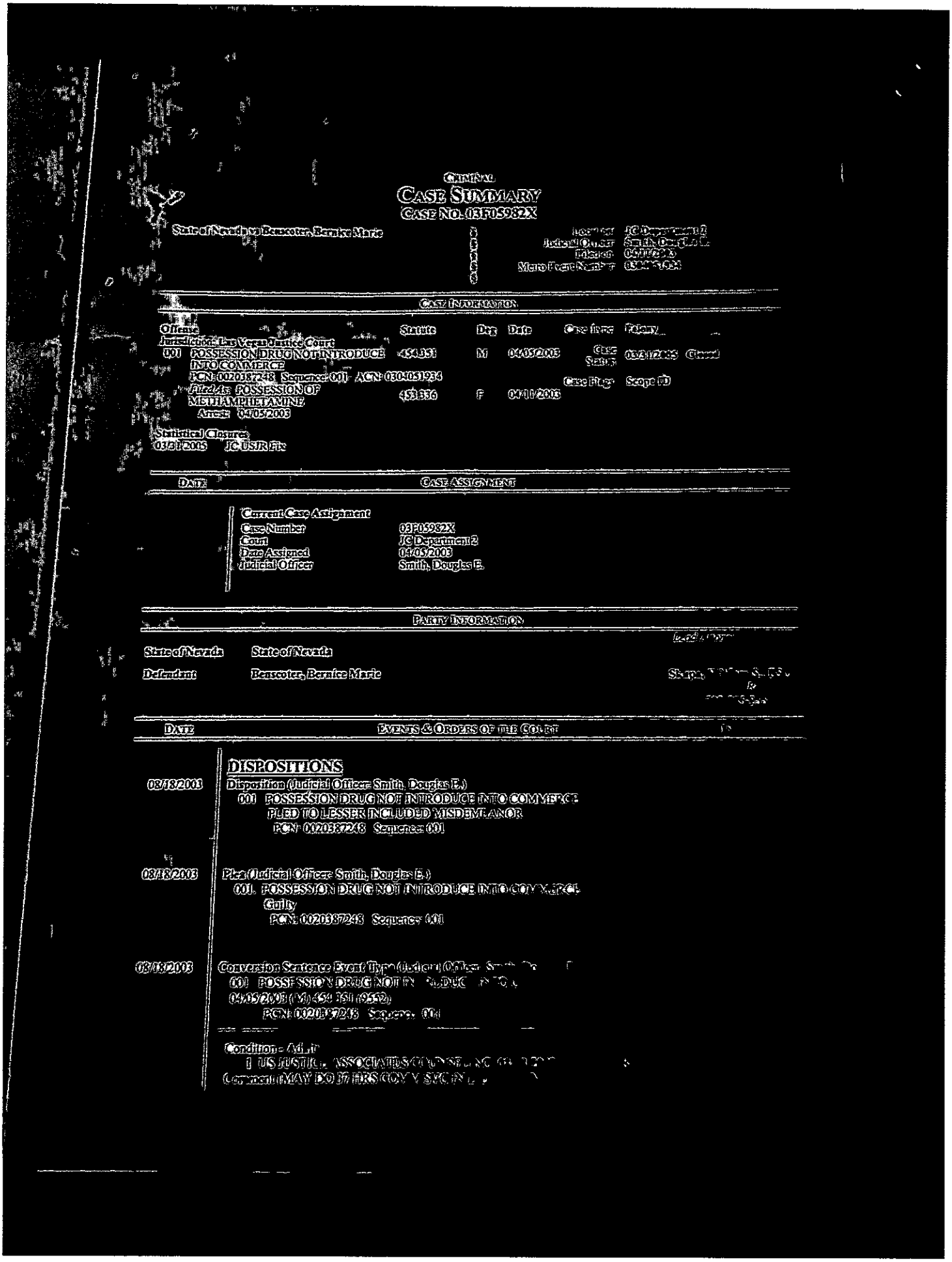
About a year ago, I was working, doing well and enjoying my job that I was at for 8 years. I loved it. It was something that I didn't mind getting up in the morning to do and I always did it well. On February 14th, 2022, I had a terrible accident that caused me to undergo massive hand surgery and hospitalization. I ended up losing one finger and the function of three others. Currently, on my left hand, I only have the utilization of my thumb. I thought life as I knew was over and was faced with a scary future. I did end up getting workers compensation and they recommended options for me to be retrained in a new career, Pharmacy technician stood out to me.

I have learned so much since being in school and have 4.0 GPA in class. I have not missed one day and make sure all my homework is completed. This is what I want to be able to do with my life. It is a chance for me to learn more, grow more and help the community.

I know I have made mistakes and faced challenges, but I appreciate you considering me for the honor of becoming a pharmacy technician in the state of Nevada.

Thank you,

"Bonnie" Bernice Benscoter



CRIMINAL

# CASE SUMMARY

## CASE NO. 03F05982X

State of Nevada vs Beauscoter, Bernice Marie

Location: JC Department 2
Judicial Officer: Smith, Douglas E.
Filed on: 04/07/2003
Metro Event Number: 03040[illegible]

### CASE INFORMATION

| Offense | Statute | Deg | Date | Case Status | Felony |
|---|---|---|---|---|---|
| Jurisdiction: Las Vegas Justice Court | | | | | |
| 001 POSSESSION DRUG NOT INTRODUCE INTO COMMERCE | 453.351 | M | 04/05/2003 | Closed | 03/31/2005 Closed |
| PCN: 0020387248 Sequence: 001 AGN: 0304051936 | | | | | |
| Amended: POSSESSION OF METHAMPHETAMINE | 453.336 | F | 04/11/2003 | Case Flags: | Scope ID |
| Arrest: 04/05/2003 | | | | | |

Statistical Closures:
03/31/2005 JC DISP Fix

### DATE — CASE ASSIGNMENT

Current Case Assignment

| | |
|---|---|
| Case Number | 03F05982X |
| Court | JC Department 2 |
| Date Assigned | 04/05/2003 |
| Judicial Officer | Smith, Douglas E. |

### PARTY INFORMATION

| | | Lead Attorney |
|---|---|---|
| State of Nevada | State of Nevada | |
| Defendant | Beauscoter, Bernice Marie | Sharon [illegible] S. [illegible] Esq. Retained [illegible] |

### DATE — EVENTS & ORDERS OF THE COURT

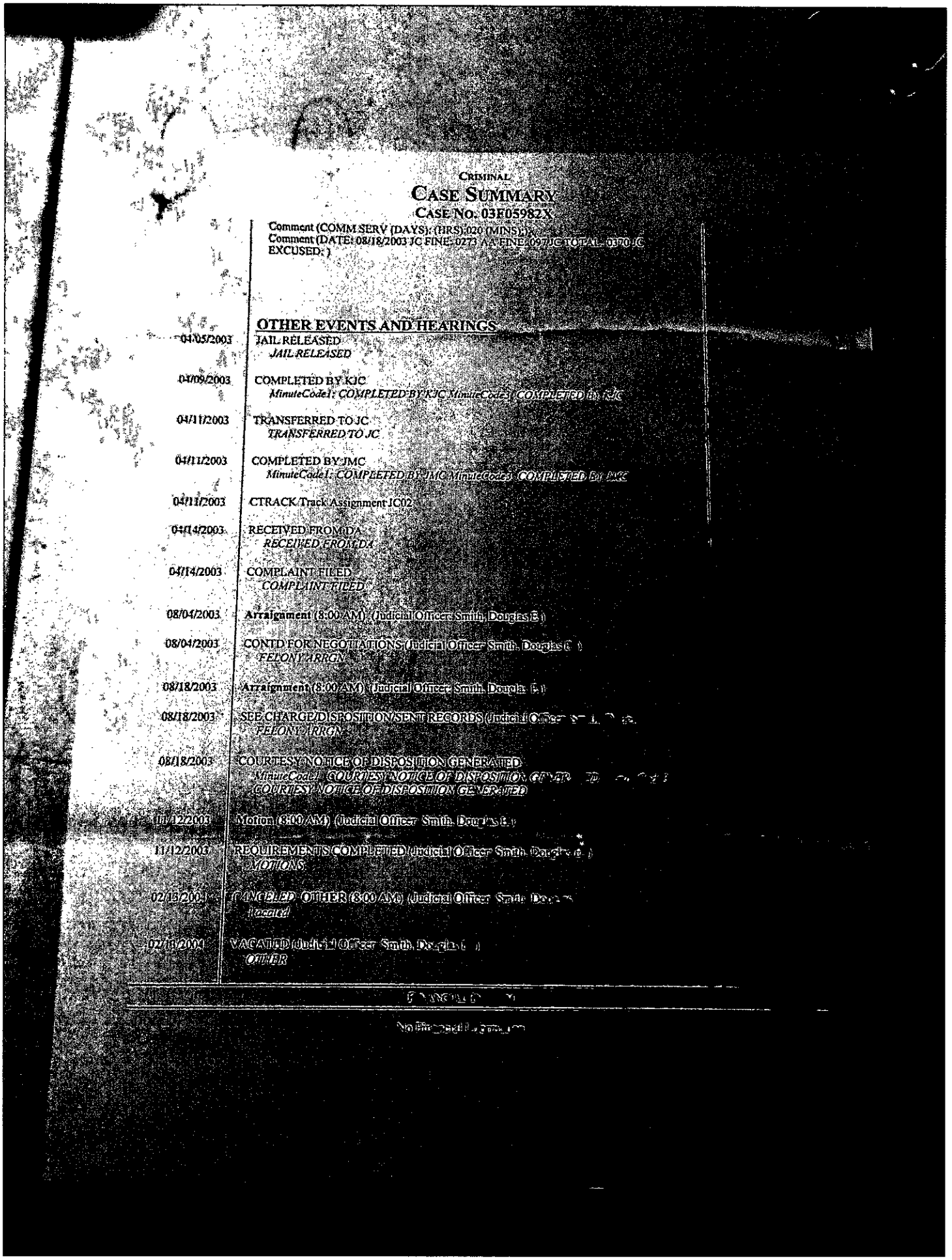
**DISPOSITIONS**

08/18/2003 Disposition (Judicial Officer: Smith, Douglas E.)
001 POSSESSION DRUG NOT INTRODUCE INTO COMMERCE
PLED TO LESSER INCLUDED MISDEMEANOR
PCN: 0020387248 Sequence: 001

08/18/2003 Plea (Judicial Officer: Smith, Douglas E.)
001 POSSESSION DRUG NOT INTRODUCE INTO COMMERCE
Guilty
PCN: 0020387248 Sequence: 001

08/18/2003 Conversion Sentence Event Type (Judicial Officer: Smith, Douglas E.)
001 POSSESSION DRUG NOT INTRODUCE INTO COMMERCE
04/05/2003 (Vio) 453.351 (M552)
PCN: 0020387248 Sequence: 001

Condition = Adult
1 US JUSTICE ASSOCIATES COUNSEL NO [illegible]
Comment: MAY DO 97 HRS COMM SVC IN LIEU



CRIMINAL

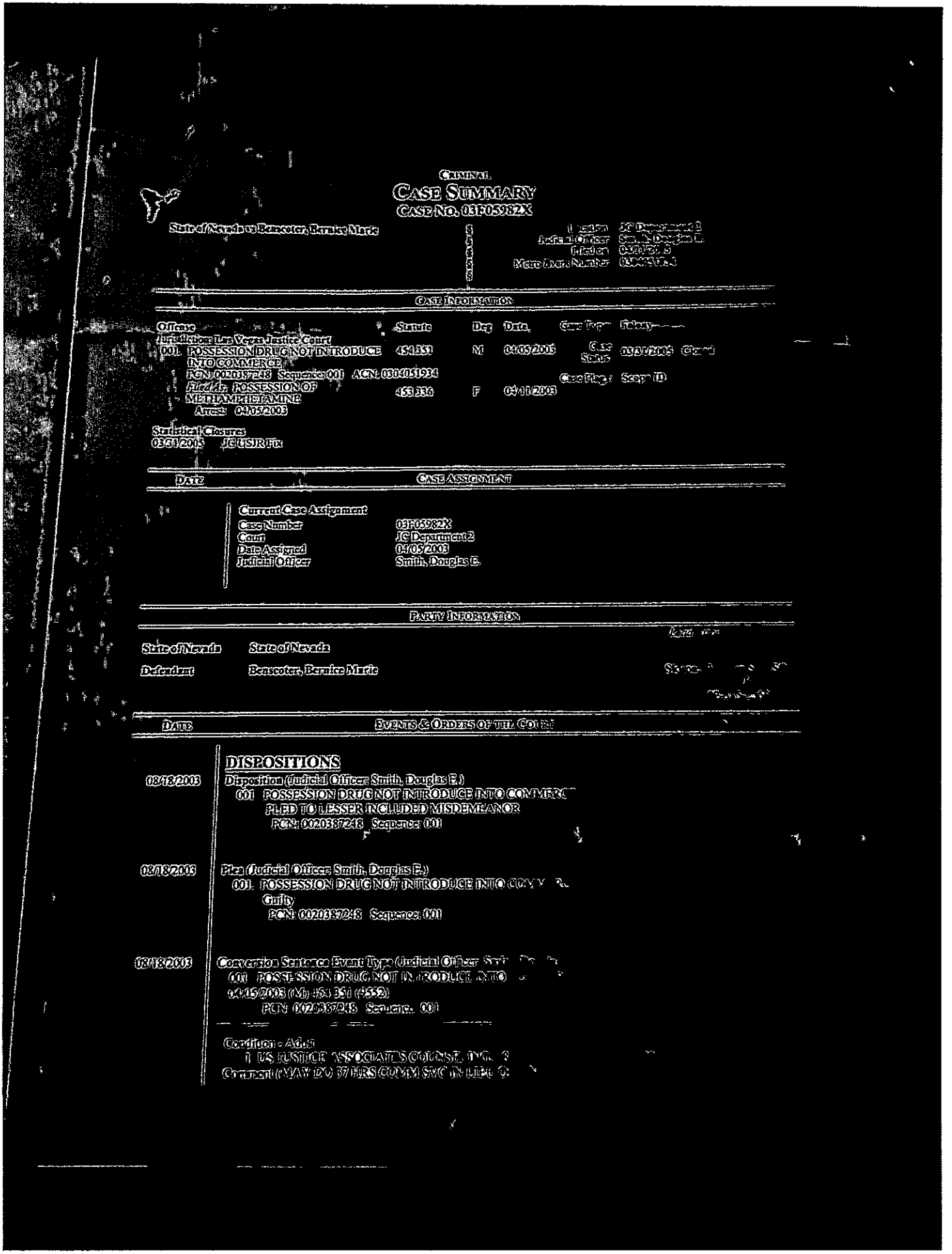
# CASE SUMMARY

## CASE NO. 03F05982X

Comment (COMM SERV (DAYS): (HRS): 020 (MINS): )
Comment (DATE: 08/18/2003 JC FINE: 0273 AA FINE: 097 JC TOTAL: 0370 JC EXCUSED: )

## OTHER EVENTS AND HEARINGS

| | |
|---|---|
| 04/05/2003 | JAIL RELEASED<br>*JAIL RELEASED* |
| 04/09/2003 | COMPLETED BY KJC<br>*MinuteCode1: COMPLETED BY KJC MinuteCode3: COMPLETED BY KJC* |
| 04/11/2003 | TRANSFERRED TO JC<br>*TRANSFERRED TO JC* |
| 04/11/2003 | COMPLETED BY JMC<br>*MinuteCode1: COMPLETED BY JMC MinuteCode3: COMPLETED BY JMC* |
| 04/11/2003 | CTRACK Track Assignment JC02 |
| 04/14/2003 | RECEIVED FROM DA<br>*RECEIVED FROM DA* |
| 04/14/2003 | COMPLAINT FILED<br>*COMPLAINT FILED* |
| 08/04/2003 | **Arraignment** (8:00 AM) (Judicial Officer Smith, Douglas E.) |
| 08/04/2003 | CONTD FOR NEGOTIATIONS (Judicial Officer Smith, Douglas E.)<br>*FELONY ARRGN* |
| 08/18/2003 | **Arraignment** (8:00 AM) (Judicial Officer Smith, Douglas E.) |
| 08/18/2003 | SEE CHARGE/DISPOSITION/SENT RECORDS (Judicial Officer Smith, Douglas E.)<br>*FELONY ARRGN* |
| 08/18/2003 | COURTESY NOTICE OF DISPOSITION GENERATED<br>*MinuteCode1: COURTESY NOTICE OF DISPOSITION GENERATED MinuteCode3: COURTESY NOTICE OF DISPOSITION GENERATED* |
| 11/12/2003 | **Motion** (8:00 AM) (Judicial Officer Smith, Douglas E.) |
| 11/12/2003 | REQUIREMENTS COMPLETED (Judicial Officer Smith, Douglas E.)<br>*MOTIONS* |
| 02/13/2004 | CANCELED OTHER (8:00 AM) (Judicial Officer Smith, Douglas E.)<br>*Vacated* |
| 02/13/2004 | VACATED (Judicial Officer Smith, Douglas E.)<br>*OTHER* |



CRIMINAL

# CASE SUMMARY

## CASE NO. 03F05982X

State of Nevada vs Benscoter, Bernice Marie

Location: JC Department 2
Judicial Officer: Smith, Douglas E.
Filed on: 04/09/2003
Metro Event Number: 030409-0544

### CASE INFORMATION

| Offense | Statute | Deg | Date | Case Type | Felony |
|---|---|---|---|---|---|
| Jurisdiction: Las Vegas Justice Court | | | | | |
| 001. POSSESSION DRUG NOT INTRODUCE INTO COMMERCE | 454.351 | M | 04/09/2003 | Case Status | 03/31/2005 Closed |
| PCN: 0020387248 Sequence: 001 ACN: 030401951934 | | | | Case Flags: | Scope ID |
| Arrest: 04/09/2003 | | | | | |
| Amd Ct: POSSESSION OF METHAMPHETAMINE | 453.336 | F | 04/11/2003 | | |

Statistical Closures
03/31/2005 JC USJR Fix

### DATE — CASE ASSIGNMENT

Current Case Assignment

| | |
|---|---|
| Case Number | 03F05982X |
| Court | JC Department 2 |
| Date Assigned | 04/09/2003 |
| Judicial Officer | Smith, Douglas E. |

### PARTY INFORMATION

| | | |
|---|---|---|
| State of Nevada | State of Nevada | Lead Attorneys |
| Defendant | Benscoter, Bernice Marie | Scope ID: |

### DATE — EVENTS & ORDERS OF THE COURT

**DISPOSITIONS**

08/18/2003 Disposition (Judicial Officer: Smith, Douglas E.)
001 POSSESSION DRUG NOT INTRODUCE INTO COMMERC
PLED TO LESSER INCLUDED MISDEMEANOR
PCN: 0020387248 Sequence: 001

08/18/2003 Plea (Judicial Officer: Smith, Douglas E.)
001. POSSESSION DRUG NOT INTRODUCE INTO COMM
Guilty
PCN: 0020387248 Sequence: 001

08/18/2003 Conversion Sentence Event Type (Judicial Officer: Smi
001 POSSESSION DRUG NOT IN RODUCE INTO
04/05/2003 (M) 454.351 (9552)
PCN: 0020387248 Sequence: 001

Condition: Adult
1 US JUSTICE ASSOCIATES COURSE, ING.
Comment: (MAY DO 37 HRS COMM SVC IN LIEU

# 14

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Pharmacist Application

**Non-Refundable $250 fee**

Rev (06/28/2022)

**Section 1: Select how will you be obtaining your Nevada Pharmacist Registration**

☐ **Examination**

☐ **Score Transfer** (Transfer your NAPLEX SCORE to Nevada within 89 days after taking your exam at https://nabp.pharmacy/ before completing this application.)

☑ **Reciprocation** (Complete NABP's Electronic Licensure Transfer Program (e-LTP) application at https://nabp.pharmacy/ before completing this application.)

Are you submitting this application to RETAKE the NAPLEX and/or MPJE? ☐ Yes ☑ No

**Section 2: General Information**

First: James Middle: Bryan Last: Arnett

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Mechanic St

City: Jeffersonville State: IN Zip: 47130

Telephone: [redacted] Email: [redacted]

**Section 3: Employment Information**

Pharmacy Name: GoGoMeds NV Pharmacy License # (if applicable): PH03487

Address: 525 Alexandria Pike, Ste. 100

City: Southgate State: KY Zip: 41071

Telephone: 888-795-5826 Email: hello@gogomeds.com

**Section 4: College of Pharmacy Information**

School Name: University of Kentucky

Address: 789 S. Limestone St

City: Lexington State: KY Zip: 40536

Country/Territory/Province: United States

Graduation Date: 1992 Degree: ☐ PharmD ☑ BS in Pharmacy ☐ Other

**Section 5: ONLY COMPLETE this section if you are applying for a Nevada Pharmacist Registration by RECIPROCATION.**

Original State of licensure/registration you are reciprocating from must be active and issued by exam (passing the NAPLEX and that state's MPJE).

State: KY License #: 010401 Date of Issuance: 07/24/1992 Expiry Date: 02/28/2024

**Section 6: List all pharmacist license/registration you have/had in other states. Use another sheet if additional space is needed.**

| State | License/ Registration # | Issued Date | Expiry Date | License/Registration Status (check applicable box) | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | Active | Inactive | Expired | Revoked | Surrendered |
| KY | 010401 | 7/24/1992 | 02/28/2024 | ✓ | | | | |
| IN | 26020513A | 7/16/2001 | 06/30/2014 | | | ✓ | | |
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| | | | | | | | | |

| Section 7: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 8: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

| Section 9: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration? | ✓ | |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state? | ✓ | |
| 3. Have you been the subject of a board citation or administrative action whether completed or pending in <u>any</u> state? | ✓ | |
| 4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state? | ✓ | |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 9 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # 1. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| 5/22/2014 | 06/19/2014 | KY | Bowling Green | Warren |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| N/A | Kentucky Board of Pharmacy |

| Reason/Charge |
|---|
| Inpatient treatment for substance use (opioid use) disorder |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| James Bryan Arnett | |

| Name of Business/Industry/Entity |
|---|
| QuestHouse (now known as JourneyPure) |

**Provide explanation below:**

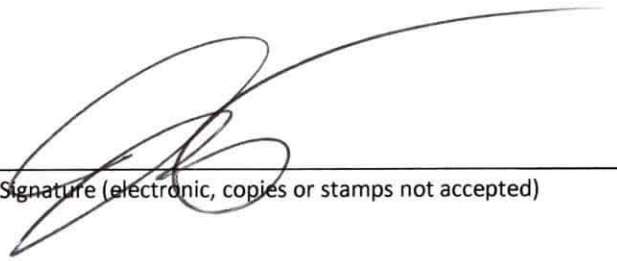
After my arrest and surrender of my pharmacist license (also pertaining to Question 2, Question 3, and Question 4), I entered treatment for substance use disorder at QuestHouse (now known as JourneyPure) on May 22, 2014. I was discharged on June 19, 2014. At that time (around May 26, 2014) I entered into a contract with the Kentucky Pharmacists Recovery Network (KYPRN).

As the reinstatement of my license required compliance with my treatment plan and KYPRN contract, I entered after-care at The Morton Center in Louisville, KY, participating in individual therapy with a counselor, as well as group therapy sessions, and weekly attendance at a health care professionals recovery group.

I attended 90 recovery meetings in my first 90 days after discharge as required by my contract with KYPRN. I then continued with my contract by attending 12 recovery meetings monthly, with a minimum of 3 each week for the duration of my contract. In Spring 2015, prior to appearing before the KYPRN Committee of the Board (with the intention of being approved to appear before the full board for license reinstatement), I saw Dr. Lon Hays, MD with the University of Kentucky Medical Center in Lexington, KY. His ultimate diagnosis of opioid use disorder in remission was required for reinstatement of my license.

In addition to the above treatment, I submitted to random drug screens for the duration of my contract.

As of this writing, I have over eight years of continuous recovery, with a "clean" or "sobriety date" of May 19, 2014.



Original Signature (electronic, copies or stamps not accepted)

2/22/2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I attest to the knowledge of and compliance with the guidelines of the Centers for Disease Control and Prevention concerning the prevention of transmission of infectious agents through safe and appropriate injection practices. NRS 639.132

I understand that Nevada law requires a registered pharmacist who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

James Bryan Arnett

Print Name

Original Signature, no copies or stamps accepted

2/22/2023

Date

| Board Use Only | Date Received: 2-28-23 | Amount: 250.00 CK. 136 |
|---|---|---|
| | NAPLEX: | MPJE: |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 9 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # 2. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| 3/21/2014 | 8/11/2018 | KY | Elizabethtown | Hardin |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| Unknown | Hardin County Circuit Court |

| Reason/Charge |
|---|
| Theft by unlawful taking, controlled substance |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| James Bryan Arnett | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

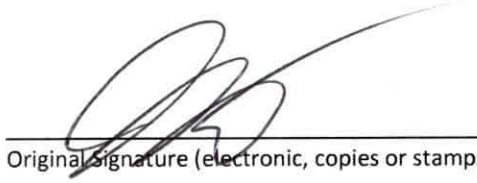
I was arrested on March 21, 2014 and charged with Theft by Unlawful Taking, Controlled Substance.

Pretrial diversion was ordered, into which I entered on or around July or August 2014. Supervised probation was mandated for one year. Upon completion of supervised probation, I continued in unsupervised probation for two more years until around August 2017. At this point, having completed three years of probation, the charge was dismissed as diverted.

As the charge was eligible for expungement, I applied for, and received the approval for expungement of the charge, with the order being entered on May 9, 2019. (See letter from John K. Spalding, my attorney in this matter.)

I do not recall exact dates aside from the date of arrest, and the date of the expungement order. Once charges are expunged in Kentucky, they are "deemed never to have happened." As I was moving in a positive direction in my life, I destroyed all the documents in my possession pertaining to this period in my life.

Attached are the above-referenced letter from my attorney, as well as documents from Kentucky Revised Statues pertaining to Pretrial Diversion, and the Effects of Successful Diversion.



Original Signature (electronic, copies or stamps not accepted)

2/~~23~~ 22/2023

Date

# Alex R. White, PLLC

Attorneys-at-Law
904 Minoma Avenue
Louisville, Kentucky 40217

Office: 502.882.7552
Fax: 502.585.3559
*Habla Español: 502.822.6089*
LouisvilleInjuires.com

Alex@ARWhiteLaw.com
Fernando@ARWhiteLaw.com
Ryan@ARWhiteLaw.com
John@ARWhiteLaw.com


August 2, 2022

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

RE: 2014 Representation of James Arnett

To whom it may concern:

In March of 2014, I was retained to represent James "Jim" Arnett in regard to a criminal case in Hardin County, Kentucky. Jim was charged with a Class D felony for alleged unlawful possession of prescription medication. Ultimately, based on the facts and evidence available to the Commonwealth, Jim was offered, and agreed, to enter a pre-trial diversion program. He successfully completed the diversion program in 2017 and his case was dismissed. Later in 2018, the Court ordered his case to be expunged. This Order was entered on May 9, 2018. Pursuant to Kentucky law, the Kentucky Constitution, and the United States Constitution, the expungement had the legal effect of erasing the charge from Jim's record and it is legally deemed to have never occurred. This case should not be counted against James or weighed in any manner regarding Jim's licensure or merit for a position. Further, all entities who ever possessed any documents or record of the case were ordered to destroy those materials within sixty (60) days of the expungement order.

As such, Jim has nothing on his record in Kentucky. He has legally never committed or been convicted of a crime in Kentucky. Neither I, nor any other Kentucky body, possess any record of a criminal charge relating to Jim.

Should you have any questions, please feel free to contact me. Thank you.

Sincerely,

John K. Spalding

**533.251 Pretrial diversion program for felony drug offender and felony offender with a history of substance abuse.**

(1) Every pretrial diversion program shall set as a condition precedent for entry into the program that any defendant charged with a Class D felony offense under KRS Chapter 218A and any defendant charged with a Class D felony offense whose criminal, medical, or mental health record indicates a present need for or benefit from substance abuse treatment participate in and demonstrate suitable compliance with the terms of a secular or faith-based substance abuse treatment or recovery program if space is available in a treatment or recovery program suitable for that defendant. The substance abuse treatment or recovery program shall be appropriate to the defendant's needs, and may include commitment to an intensive outpatient program, a residential substance abuse treatment or recovery facility, or the intensive secured drug abuse treatment program developed under KRS 196.285. Consideration may be given, in whole or in part, to a defendant's participation in drug monitoring or a substance abuse treatment or recovery plan ordered under KRS 431.518 as evidence of suitable compliance under this section.

(2) The court may waive compliance with subsection (1) of this section if the defendant can show that exigent circumstances exist sufficient to justify diversion program participation without a prior demonstration of treatment compliance.

(3) The court may continue in effect any nonfinancial conditions of pretrial release imposed under KRS 431.520 or 431.525 and may hold the case in abeyance during the period of time the defendant is attempting treatment or recovery prior to diversion under subsection (1) of this section.

(4) The court may allow a person charged with a Class C felony to participate in a secular or faith-based substance abuse treatment or recovery program under subsection (1) of this section or obtain a waiver under subsection (2) of this section. If the person is successful in the program or is waived, the person shall be eligible for entry into the pretrial diversion program under the same terms, conditions, and limitations as a Class D felon.

**Effective:** March 24, 2009

**History:** Created 2009 Ky. Acts ch. 96, sec. 4, effective March 24, 2009.

**533.258 Effects of successful completion of pretrial diversion agreement.**

(1) If the defendant successfully completes the provisions of the pretrial diversion agreement, the charges against the defendant shall be listed as "dismissed-diverted" and shall not constitute a criminal conviction.

(2) The defendant shall not be required to list this disposition on any application for employment, licensure, or otherwise unless required to do so by federal law.

(3) Pretrial diversion records shall not be introduced as evidence in any court in a civil, criminal, or other matter without the consent of the defendant.

**Effective:** July 15, 1998

**History:** Created 1998 Ky. Acts ch. 606, sec. 90, effective July 15, 1998.

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 9 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # 3. Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| 11/7/2014 | 8/11/2021 | KY | Frankfort | Franklin |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| 14-0060 | Kentucky Board of Pharmacy |

| Reason/Charge |
|---|
| Agreed Order of Suspension/Agreed Order of Reinstatement |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| James Bryan Arnett | |

| Name of Business/Industry/Entity |
|---|
| |

**Provide explanation below:**

Relating to Question 1, Question 2, and Question 4.

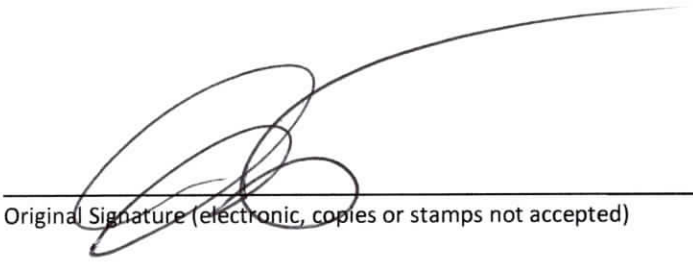
I surrendered my Kentucky Pharmacist License #010401 on or around March 24, 2014.

On November 7, 2014, my pharmacist license was officially suspended by the Kentucky Board of Pharmacy.

Upon completion of the stipulations in my order of suspension, I appeared before the Kentucky Pharmacist Recovery Network (KYPRN) Committe and the full Board in May, 2015. At this time, I was approved for reinstatement of my license with stipulations as included in the attached Agreed Order or Reinstatement and Order of Suspension.

As of August 11, 2015, my license was reinstated with stipulations as included in the attached Agreed Order.

Effective August 11, 2021, my license is no longer on probation, and is "clear and active," albeit with the prior discipline being viewable on the Kentucky Board of Pharmacy webisite. The participation in KYPRN being part of my Agreed Order, the release letter from the Director of KYPRN is attached.



Original Signature (electronic, copies or stamps not accepted)

2/22/2023

Date

**Commonwealth of Kentucky**
**Kentucky Board of Pharmacy**
**Case Number 14-0060**

IN RE: PETITION FOR REINSTATEMENT OF JAMES ARNETT

***Agreed Order of Reinstatement with Restrictions***

Come the parties, the Kentucky Board of Pharmacy (hereafter "Board") and James Arnett (hereafter "Respondent"), and both being fully informed regarding the matter set forth herein, state as follows:

(1) Pursuant to KRS Chapter 315, the Board is authorized to regulate and control all matters related to pharmacists.

(2) Respondent entered into an *Agreed Order of Suspension* with the Board on or about November 7, 2014 (incorporated by reference herein).

(3) Respondent is currently under contract with KYPRN, has complied fully with the terms of his *Agreed Order of Suspension*, and desires reinstatement of his license.

(4) The Board agrees to license Respondent to practice the profession of pharmacy so long as his license is issued with conditions and restrictions. Respondent agrees to each of the conditions and restrictions as stated in this *Agreed Order of Reinstatement with Restrictions*.

WHEREFORE, IT IS HEREBY AGREED AND ORDERED THAT:

(A) Pursuant to KRS 315.050 and 315.121, Respondent's pharmacist license shall be issued upon paying the requisite fees, tendering proof of completion of required continuing education, and submitting a completed application to the Board;

(B) Respondent's pharmacist license is placed on probation for five (5) years and is subject to the following terms and conditions:

(1) Respondent shall work a maximum of forty-five hours per week or ninety hours within two weeks, with a maximum of fifty hours in any seven consecutive days, with no overtime;
(2) Respondent shall provide a copy of this *Agreed Order of Reinstatement* to all Pharmacists-in-Charge (PIC) and all employers, wherever Respondent is employed as a pharmacist or in a pharmacy;
(3) Respondent shall not engage in the practice of pharmacy in any other state or jurisdiction;
(4) A perpetual inventory is required at all places of employment and pharmacies owned, in whole or in part, for C-II's, with electronic tracking of C-III's, C-IV's, C-V's, and this perpetual inventory/electronic tracking must be made available to the Board on request and audits may be conducted;
(5) Respondent shall sign a *Monitoring Agreement* with Kentucky Pharmacist Recovery Network (KYPRN), which includes a drug counselor and/or mental health counselor if indicated by KYPRN. The aftercare contract with KYPRN shall be in full force and effect for as long as Respondent is under the terms of this *Agreed Order of Reinstatement,* and Respondent shall notify the Board and KYPRN of any violation of this *Agreed Order of Reinstatement* or KYPRN contract, within twenty-four hours;
(6) Respondent shall notify the Board of change of home address, telephone number and/or email within seven days of change;
(7) Respondent shall provide to the Board a signed release granting the Board and KYPRN access to all medical records and patient information;
(8) Respondent shall attend AA or NA meetings no less than six times per two weeks or twelve meetings per calendar month, which shall include a minimum of two meetings per week and shall provide the Board and KYPRN with monthly written reports of all AA/NA meetings;
(9) Respondent shall agree to provide a minimum of six random urine or other body fluid or hair samples at the discretion of PRN, the Board, or any other monitoring body for licit and illicit drugs of abuse and over-the-counter medications each year during the probation, with all expenses to be paid by Respondent. Production of these samples shall be observed. Respondent shall provide copies of any results of these screens ordered by anyone to the KYPRN Chair and the Board. Respondent understands that it is his responsibility to notify the KYPRN Chair, the testing company, and the Board office of anything that may affect his availability for screens (e.g. vacations, travel, family obligations and so on prior to the events). The agency that provides the collection shall be approved by the KYPRN Chair. A missed screen may be cause for reporting such to the Board. Any positive screen that is a violation of this *Agreed Order of Reinstatement* or KYPRN contract shall be communicated to the Board by the KYPRN Chair within twenty-four hours. A report indicating a presumptive presence shall constitute a conclusive basis, without the necessity of a hearing, for a determination that Respondent is not in compliance with the terms of this *Agreed Order of Reinstatement;*
(10) Respondent shall agree to abstain from any and all mood-altering chemicals (including but not limited to alcohol (i.e.-ethyl alcohol or ethanol),

marijuana, tranquilizers, sedatives, stimulants, narcotics, opioids, including tramadol, nulbuphine, soporifics, androgenic steroids, scheduled and/or unscheduled drugs, mood altering over-the-counter medications, herbals, dietary supplements and any other known addictive drug) except as prescribed by his physician and only after consultation with the Director of KYPRN. If any mood altering and/or potentially addictive medications are required or recommended by his physician, Respondent shall notify the KYPRN Chair in advance and provide documentation of the need for the medication (i.e.-a copy of the prescription or note from the prescribing practitioner) within three days. If the need for the medication is ongoing, Respondent shall renew and verify with the KYPRN Chair every ninety (90) days. Respondent also agrees to avoid exposure to anything that will cause his drug test to be positive. In that regard Respondent shall avoid such items as "hemp oil" and "coca tea" and Respondent shall not consume poppy seeds (which can be found hidden in curry sauces, breads, salad dressings, and in or on other foods). Respondent shall not use ethyl alcohol in any form (including "alcohol free wine or beer," over-the-counter drugs containing alcohol (cough syrups, Nyquil or other similar OTC drug or supplement), mouthwash or other hygiene products containing ethanol, foods containing ethanol (desserts, vanilla extracts, etc.) communion wine, sanitizing hand or body gels (Purell or other), or any other form of ethyl alcohol. Intentional use of any of these products or medications without a practitioner's order is a violation of this *Agreed Order of Reinstatement* and KYPRN contract. When Respondent signs this *Agreed Order of Reinstatement* and KYPRN contract he gives up the right to self medicate with the exception of single entity OTC NSAIDS and acetaminophen. A report indicating a presumptive presence shall constitute a conclusive basis, without the necessity of a hearing, for a determination that he is not in compliance with the terms of this *Agreed Order of Reinstatement;*

(11) Respondent is precluded from accepting a position of Pharmacist-in-Charge, Preceptor, or from exercising Power-of-Attorney for purposes of purchasing controlled substances;

(12) Respondent shall keep the Board advised at all times of his places of employment and shall only practice at a location and a work schedule that has received prior approval of the Board or its President;

(13) Respondent shall not work at a pharmacy owned, in whole or in part, by him or another member of his family and Respondent shall not possess a key to a pharmacy owned, in whole or in part by him or another member of his family. Respondent shall not be on the premises of any pharmacy owned, in whole or in part, by him or another member of his family. During his probation Respondent shall have prior approval to own a new pharmacy, in whole or in part, by the Board or Board President;

(14) For two years following execution of this *Agreed Order of Reinstatement*, the Board shall conduct quarterly inspections at all locations of Respondent's employment; the costs of which, not to exceed $500 per inspection, shall be paid by Respondent to the Board within thirty (30) days of invoicing by the Board. After two years, inspections shall be conducted on a semi-annual basis. Costs shall be determined as time, travel costs, and mileage charges of the inspector(s);

(15) Respondent shall obtain all of his prescriptions and those of his family at a pharmacy designated in writing to the Board and shall not dispense any drugs for himself or his family;
(16) Respondent shall attend within one (1) year of the entry of this *Agreed Order* either the University of Utah School on Alcoholism and other Drug Dependencies, CAPTASA, or the Southeastern PRN Meeting and shall provide a certificate of completion to the Board;
(17) Respondent shall provide monthly written self performance evaluations to the KYPRN Chair and the Board and shall make all appearances before the KYPRN Committee as requested, including an annual appearance at the KYPRN meeting closest to the anniversary date of reinstatement for each year while on probation;
(18) If Respondent commits any other act that results in a violation of a federal or state pharmacy or drug statute or regulation, the Board reserves the right to issue a Complaint against Respondent's license and impose any applicable penalties pursuant to KRS Chapter 315;
(19) Respondent agrees that a violation of this *Agreed Order of Reinstatement* shall cause him to automatically lose his license to practice pharmacy for not less than five years and one day and shall require Respondent to petition the Board for reinstatement only after he has been approved to take and then successfully passes the entire Kentucky Board of Pharmacy licensure examination (NAPLEX and MPJE). After a minimum of five years and one day, Respondent agrees to provide, with his petition for reinstatement of his Kentucky pharmacist license, documentation from a certified addictionologist and an approved treatment provider that Respondent has documented not less than five (5) years and one (1) day of continued sobriety and that in the professional opinion of the addictionologist and the treatment provider that Respondent is then currently able to practice the profession of pharmacy with reasonable skill, care, and safety to patients.
(20) Respondent shall not seek to amend or modify this *Agreed Order of Reinstatement*, except as expressly provided in this *Agreed Order of Reinstatement.* This *Agreed Order of Reinstatement* constitutes the entire agreement between the parties and Respondent is not relying on any other agreement or representation of any kind, verbal, or otherwise;
(21) By practicing pursuant to this *Agreed Order of Reinstatement* and by his signature on this *Agreed Order of Reinstatement*, Respondent expressly acknowledges that he was fully and completely informed of his right to due process and right to legal counsel, that he fully understands those rights, and that he knowingly, voluntarily, and willingly agrees to waive those rights, and that he will practice the profession of pharmacy in the Commonwealth in conformity with the requirements of this *Agreed Order of Reinstatement* and all applicable pharmacy and drug laws;
(22) The above information shall be reported to the National Association of Boards of Pharmacy ("NABP"), and is subject to disclosure under the Kentucky Open Records Act; and

(23) A fully executed copy of the *Agreed Order of Reinstatement* is evidenced by the date it is signed by the President of the Kentucky Board of Pharmacy.

Joel Thornbury, President
Kentucky Board of Pharmacy

Date 8/3/15

James Arnett, Respondent

Date 7/10/2015

KYPRN 1501 Alexandria Pike, Fort Thomas, KY 41075| 502.230.8442 | www.kyprn.com

11 August 2021

Re:
James Arnett, PharmD
[redacted] E 3rd St Apt. [redacted]
Long Beach, CA
90802

To whom it may concern,

I am writing to inform you of Dr. James Arnett's successful discharge from Kentucky Professionals Recovery Network (KYPRN). James was ordered by the Kentucky Board of Pharmacy to participate with KYPRN for a period of 5 years, which he has completed as of this letter. During the course of his time with KYPRN, James attended 12 step meetings regularly, and submitted to regular drug screens as required by his KYPRN agreement. James provided KYPRN with monthly self reports. KYPRN had no issues with James' compliance for the duration of his contract.

Please feel free to reach out if you have any questions on Dr. Arnett's participation with KYPRN.

Sincerely,

Emily Caporal, PharmD
Director-KYPRN

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 9 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # 4 . Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| 11/7/2014 | 8/11/2021 | KY | Frankfort | Franklin |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| 14-0060 | | Kentucky Board of Pharmacy | | |
| **Reason/Charge** | | | | |
| Agreed Order of Suspension | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| James Bryan Arnett | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

Relating to Question 1, Question 2, and Question 3.

After surrender of my pharmacist license around March 24, 2014, an Agreed Order of Suspension was entered on November 7, 2014.

Upon completion of relicensure requirements, an Agreed Order of Reinstatement was entered, and my license reinstated effective August 11, 2015.

I have completed all the requirements of my Agreed Order, as well as all stipulations of my contract with KYPRN. As such, I was released from KYPRN on August 11, 2021, and my license is now "clear and active," albeit with the prior Board action viewable on the Kentucky Board of Pharmacy website.

Original Signature (electronic, copies or stamps not accepted)

2/22/2023
Date

**COMMONWEALTH OF KENTUCKY**
**Kentucky Board of Pharmacy**
**Case No. 14-0060**

2014 SEP 30 A 7:46

IN RE: James Arnett
[redacted] Cherokee RD APT [redacted]
Louisville KY 40205
Pharmacist License No. 010401

***Agreed Order of Suspension***

The Kentucky Board of Pharmacy ("Board") based upon the information presented to it and being sufficiently advised, and James Arnett ("Arnett") hereby agree to the entry of this *Agreed Order of Suspension* in an effort to provide a framework for the reinstatement of Arnett's license to practice the profession of pharmacy after meeting conditions designed to provide circumstantial guarantees that Arnett is able to practice the profession with reasonable skill, safety and competence to patients.

**Stipulations of Fact**

The parties stipulate to the following factual statements that serve as the factual basis for this *Agreed Order of Suspension*:

1. Arnett at all times material hereto is and has been licensed in the Commonwealth as a pharmacist having been issued license number 010401.

2. On or about March 19, 2014, Arnett was observed on video diverting hydrocodone/acetaminophen tablets.

3. On or about March 21, 2014, Arnett admitted, in a written statement, to diverting hydrocodone/acetaminophen, Klonopin, and Effexor XR.

4. On or before April 1, 2014, Arnett surrendered his pharmacist license to the Board by mail.

**Stipulated Conclusions of Law**

The parties stipulate to the following Conclusions of Law, which serve as the legal basis for this *Agreed Order of Suspension*:

1. Arnett's license to practice pharmacy in the Commonwealth is subject to regulation and discipline by the Kentucky Board of Pharmacy;

2. There is probable cause to believe that Arnett has a mental or physical incapacity that prevents Arnett from engaging in the practice of pharmacy with reasonable skill, competence, and safety to the public; and

3. The Board may discipline Arnett pursuant to KRS 315.121(1)(b).

**Order of Suspension**

Based upon the foregoing stipulated facts and conclusions of law, the Board and Arnett agree to resolve this matter without further administrative proceedings. Accordingly:

1. Arnett agrees he will not attempt to reinstate his Kentucky pharmacist license until he is able to document through KYPRN completion of an approved 28 day in-house treatment program and a minimum of six (6) months continued sobriety from the date of signing his KYPRN.

2. Arnett agrees to provide, with his petition for reinstatement of his Kentucky pharmacist license, documentation from a certified addictionologist and an approved treatment provider that he has documented not less than six (6) months of continued sobriety, the attendance of ninety (90) AA or NA meetings in ninety (90) days and that in the professional opinion of the addictionologist and the treatment provider that Arnett is then currently able to practice the profession of pharmacy with reasonable skill, care, and safety to patients.

3. Arnett agrees to appear before the Board when he requests reinstatement and acknowledges that the Board may grant or deny such a petition for reinstatement, with appropriate conditions.

Cathy Hanna, President
Kentucky Board of Pharmacy

11-7-14
Date

James Arnett

9/23/2014
Date

# 15

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## CONTROLLED SUBSTANCE APPLICATION

**Non-Refundable $200 fee**

Rev (01/05/2023)

**(This application cannot be used by PA's or APRN's)**

**Select the Controlled Substance Schedules you are applying to prescribe (optometrists are limited to schedules III, IV, and V.)**

☐ Schedule I ☑ Schedule II ☑ Schedule III ☑ Schedule IV ☑ Schedule V

**Section 1: Personal Information**

First: Ronald Middle: David Last: Smith

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Home Address: [redacted] Willis St

City: Bristol State: CT Zip: 06010

Telephone: [redacted] Email: david.smith@solutionpediatrics.com

Degree: MD Practitioner License #: 11778 Specialty: Pediatrics

(You MUST have a current and active practice license with your respective BOARD to apply for and maintain a controlled substance registration.)

**Section 2: Practice Information (A practice address is required for processing of your application.)**

Practice Name (if any): Solution Pediatrics

Practice Address: 2280 Paseo Verde Pkwy Suite #: 100

City: Henderson State: NV Zip: 89052

Telephone: 702-998-8009 Fax: _____ Email: david.smith@solutionpediatrics.com

| Section 3: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✓ |

| Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✓ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | |

| Section 5: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | ✓ | |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state? | ✓ | |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? | ✓ | |
| 4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state? | ✓ | |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # 2 . **Provide all the following *where applicable*:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| 6/20/2019 | 1/5/2023 | NV | Las Vegas | Clark |
| Case # | | Governing, licensing, Arresting Presiding Body/Agency/Court | | |
| | | US Court Nevada District | | |
| Reason/Charge | | | | |
| Plead guilty to misdemeanor possession of controlled substance--2 counts | | | | |
| Plaintiff/Defendant/Claimant/Respondent | | | Lawsuit/Arbitration/Bankruptcy | |
| | | | | |
| Name of Business/Industry/Entity | | | | |
| | | | | |

**Provide explanation below:**

Regarding Question 1: I have been diagnosed with both stimulant use disorder and alcohol use disorder, both in remission. I have a 5 year monitoring agreement with the state of North Carolina that runs through June of 2025. I have been in successful compliance and sober since February of 2020.

Regarding question 2: Was working in an opiate treatment clinic, Detoxification Solutions. The clinic was under investigation starting in Sept of 2018. I began work there in late Feb, 2019. The owner was an unlicensed practitioner, writing scripts for buprenorphine under the medical director's license (Dr. Chad Hall) and improperly obtaining and storing buprenorphine for the clinic. I was indicted initially under several felony charges that included assisting in obtaining the buprenorphine for the clinic, but those were dismissed prior to my plea agreement. The case was settled with a plea agreement that included the final charges of misdemeanor possession of a controlled substance as noted above. At the time of my arrest, I voluntarily surrendered my NV DEA license and my supervised release conditions required that I not prescribe controlled substances. There were stipulations made allowing my use of controlled substances on an inpatient basis however. I had licenses in three other states that expired while the case was pending. I voluntarily relinquished one (South Dakota) and the other two simply expired.

Regarding Questions 3 and 4: I have been subject to a consent agreement in the state of North Carolina that was related to both the case noted in questions 2 and a relapse of my alcohol use disorder. Initially, the agreement restricted me from prescribing controlled substances as this was a part of my supervised release with the federal court as of June 2019. Subsequent to the finalizing of my plea agreement, the restriction on controlled substance prescribing has been lifted and the decree only requires that I maintain compliance with my monitoring agreement. Subsequent to this agreement with NC enacted in November of 2020, the state of Ohio suspended my license (although it was inactive at the time) and conditioned reinstatement on having an unrestricted license in the state of North Carolina and the resolution of my federal case. Discussion with the Ohio board regarding reinstatement are ongoing.

Original Signature (electronic, copies or stamps not accepted)

8/14/23
Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

R. David Smith — Print Name (First, Last)

8/14/23 — Date

R. David Smith — Original Signature (electronic, copies or stamps not accepted)

8/14/23 — Date

Board Use Only: Date Processed: _____ Amount: 200-cc

BEFORE THE NEVADA STATE BOARD OF PHARMACY
NEVADA STATE BOARD OF PHARMACY,
Petitioner,
v.
RONALD SMITH, MD,
Certificate of Registration No. CS13980,
Respondent.
CASE NO. 20-212-CS-S

Jeffrey J. Whitehead, General Counsel for Ronald Smith, MD., hereby petitions the Board for ***a temporary license*** and for ***reinstatement to be heard*** on the next Board hearing on September 6-7, 2023, based on the following:

1. Dr. Smith has paid for his indiscretion and has had all judicial impediments removed from reinstatement of all restrictions to his prescribing privileges.

Attached is the proof that the judicial requirements have been satisfied. The court specifically noted that it will not restrict his returning to addiction treatment or to pain management if he so desires. Although Dr. Smith has never practiced pain management and has no desire to return to the medication assisted treatment of addiction, this shows that the court has confidence in Dr. Smith's ability to return the practice of medicine with controlled substance prescribing privileges.

Subsequently, the state of North Carolina has also removed the restriction on his controlled substance prescribing that was put in place in a consent decree in November of 2020. This modification was granted in March of 2023 and is included herewith.

2. Dr. Smith needs a temporary prescribing license in order to obtain employment.

A temporary license would allow Dr. Smith to be able to gain employment and earn a living. Being able to prescribe controlled substances is a necessity for most employers to consider hiring and it is a condition for obtaining staff privileges at most if not all hospitals in the state of Nevada. Being that his primary practice has always been hospital-based, obtaining staff privileges is essential for him. Having a controlled substance license is also a condition of being able to apply for employment with locum tenans and telemedicine practices. Because Dr. Smith must have a state-controlled substance license as the first step in being able to apply for a DEA license for the state of Nevada, his ability to move forward is severely limited without it as this renders him effectively unemployable. Although the one-year restriction on his applying for formal reinstatement does not expire until July 13. 2023, we respectfully request that the Board also consider that by that time, Dr. Smith will have been without controlled substance prescribing privileges from the Nevada Board of Pharmacy since September of 2019, an effective suspension of nearly four years

3. Dr. Smith presents the following statement of contrition

"I sincerely regret the mistakes I made while working for Detoxification Solutions from March 2019 through June 2019. I would like to note that prior to this event, I had worked and prescribed in the state of Nevada for 14 years without incident or concern. The nearly four years I

have spent with my privileges and practice restricted has brought significant and severe consequences. I have had ample time to reflect on how circumstances came to this point and can assure the Board that these errors will not recur and that I will never be in this situation again. I am grateful for your time and consideration." Ronald D. Smith, M.D.

Signed this 14th day of July 2023.

*/s/ Jeffrey J Whitehead*
*/s/ Ronald D. Smith, M.D.*

RECEIVED
JUL 17 2023
NEVADA STATE BOARD OF PHARMACY

FILED
JUL 13 2022
NEVADA STATE BOARD
OF PHARMACY

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

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|---|---|
| **NEVADA STATE BOARD OF PHARMACY,**<br>**Petitioner,**<br>**v.**<br>**RONALD SMITH, MD,**<br>**Certificate of Registration No. CS13980,**<br>**Respondent.** | **CASE NO. 20-212-CS-S**<br>**STIPULATION AND ORDER** |

Brett Kandt, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondent Ronald Smith, MD, Certificate of Registration No. CS13980, by and through counsel, Mark H. Hutchings, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. The Board has jurisdiction over Respondent and this matter.

2. On or about October 23, 2020, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing, and Respondent filed an Answer and Notice of Defense to the Accusation.

3. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to him pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives his rights to a

hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to him by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Respondent admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in the Accusation, *to wit*:

A. On June 20, 2019, Respondent surrendered his DEA Certificate of Registration No. BS9687116 to the U.S. Drug Enforcement Administration by executing a DEA Form 104, entitled "Surrender for Cause";

B. On or about July 22, 2019, Respondent was served with notice that his surrender for cause operated as an immediate suspension of his Certificate of Registration No. CS13980 with the Board pursuant to NRS 639.2107; and

C. By surrendering his DEA Certificate of Registration No. BS9687116 for cause, Respondent has admitted to failing to comply with the Federal requirements pertaining to controlled substances, has committed an act that would render his registration inconsistent with the public interest, is no longer authorized by Federal law to dispense controlled substances, and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

7. In order to resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent stipulate to the following penalties:

A. The certificate of registration of Respondent Ronald Smith, MD, Certificate of Registration No. CS13980, is hereby revoked pursuant to NRS 453.241(l)(b);

B. Respondent may not possess (except pursuant to the lawful order of a practitioner), administer, prescribe or dispense a controlled substance until he has petitioned the Board for reinstatement pursuant to NRS 639.257 and the Board reinstates his certificate of registration;

C. Pursuant to NRS 622A.410(1) and 639.257(1), Respondent may not petition for reinstatement of his certificate of registration for a period of one (1) year from the effective date of this Order; and

D. In the event Respondent applies for reinstatement of his certificate of registration, or applies for any other certificate, license or permit with the Board, he shall appear before the Board to answer questions and give testimony regarding his application, his compliance with this Order, and the facts and circumstances underlying this matter.

8. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapters 453 and 639.

9. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on July 13, 2022. Respondent or his counsel will appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting.

10. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

11. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

12. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

**Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.**

**AGREED:**

**Signed this 6th day of June, 2022**

**RONALD SMITH, MD,**
**Certificate of Registration No. CS13980**

**Signed this 7th day of June, 2022**

**BRETT KANDT, ESQ.**
**General Counsel**
**Nevada State Board of Pharmacy**

**APPROVED AS TO FORM AND CONTENT**
**this 6th day of June, 2022**

**MARK H. HUTCHINGS, ESQ.**
**Counsel for Respondent**

## DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Ronald Smith, MD, Certificate of Registration No. CS13980, in Case No. 20-212-CS-S and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

**IT IS SO ORDERED.**

Entered this 13th day of July, 2022.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

FILED
OCT 23 2020
NEVADA STATE BOARD OF PHARMACY

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

| | |
|---|---|
| **NEVADA STATE BOARD OF PHARMACY,**<br>**Petitioner,**<br>**v.**<br>**RONALD SMITH, MD,**<br>**Certificate of Registration No. CS13980,**<br>**Respondent.** | **CASE NO. 20-212-CS-S**<br>**NOTICE OF INTENDED ACTION AND ACCUSATION** |

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under Nevada Revised Statutes ("NRS") 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

## JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Ronald Smith, MD, held a Nevada controlled substance registration, Certificate of Registration No. CS13980, issued by the Board.

## FACTUAL ALLEGATIONS

2. On June 20, 2019, Respondent surrendered his DEA Certificate of Registration No. BS9687116 to the U.S. Drug Enforcement Administration by executing a DEA Form 104, entitled "Surrender for Cause" (DEA Surrender for Cause).

3. By executing the DEA Surrender for Cause, Respondent acknowledged in pertinent part the following:

> In view of my alleged failure to comply with the Federal requirements pertaining to controlled substances or list 1 chemicals, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices on my part, I hereby surrender for cause my Drug Enforcement Administration (DEA) Certification of Registration.

4. On or about July 22, 2019, Board staff served Respondent with notice that his surrender of his DEA Certificate of Registration No. BS9687116 for cause operated as an

immediate suspension of his Certificate of Registration No. CS13980 with the Board pursuant to NRS 639.2107.

**FIRST CAUSE OF ACTION**

**Surrender of DEA Registration for Cause**

5. By surrendering his DEA Certificate of Registration No. BS9687116 for cause, Respondent has admitted to failing to comply with the Federal requirements pertaining to controlled substances, has committed an act that would render his registration to dispense controlled substances inconsistent with the public interest, is no longer authorized by Federal law to dispense controlled substances, and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

6. By surrendering his DEA Certificate of Registration No. BS9687116 for cause, the suspension of Respondent's Certificate of Registration No. CS13980 pursuant to NRS 639.2107 is subject to review by the Board pursuant to NRS 453.236(1) and NRS 639.255(1)(c).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 23rd day of October, 2020.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

## NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

**BEFORE THE NEVADA STATE BOARD OF PHARMACY**

| | |
|---|---|
| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br>**v.**<br><br>**RONALD SMITH, MD,**<br>**Certificate of Registration No. CS13980,**<br><br>**Respondent.** | **CASE NO. 20-212-CS-S**<br><br>**STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING** |

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

I.

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

II.

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

III.

**The Board has scheduled your hearing on this matter for Wednesday, December 2, 2020, 9:00 a.m. or soon thereafter. Pursuant to Governor Steve Sisolak's Emergency Directive 006, there will be no physical location for this meeting. The meeting can be listened to or viewed live over Zoom.**

**Via Videoconference at Zoom: https://zoom.us/j/5886256671**
**or**
**Via Teleconference at 1 (669) 900-6833**
**Meeting ID: 588 625 6671**

IV.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

V.

Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 23rd day of October, 2020.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

| | |
|---|---|
| **NEVADA STATE BOARD OF PHARMACY,**<br><br>**Petitioner,**<br><br>**v.**<br><br>**RONALD SMITH, MD,**<br>**Certificate of Registration No. CS13980,**<br><br>**Respondent.** | **CASE NO. 20-212-CS-S**<br><br>**ANSWER AND NOTICE OF DEFENSE** |

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2020.

**RONALD SMITH, MD**

# 16

Y

# NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

## Physician Assistant (PA) – Prescribe/Controlled Substance Registration Application

Rev (01/05/2023)

**What types of drug(s) will you be prescribing?**

☐ Dangerous Drugs ONLY (Non-Refundable $80 Fee) (PR)

☒ Dangerous Drugs AND Controlled Substances (CS) I, II, III, IV and/or V (Non-Refundable $200 Fee) (CS)

Select the Controlled Substance Schedules you are applying to prescribe

☐ Schedule I ☒ Schedule II ☒ Schedule III ☒ Schedule IV ☒ Schedule V

**Section 1: Personal Information (NAC 639.272)**

First: Aaron Middle: Harris Last: Kuehl

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Home Address: [redacted] Splendor Ridge Ave

City: Las Vegas State: Nevada Zip Code: 89135

Telephone: [redacted] Email: [redacted]

PA License #: PA2797 Specialty: Family Practice

(You **must have a current and active license** with the Nevada State Board of Medical Examiner or Nevada State Board of Osteopathic Medicine to apply for and maintain a Prescribe or CS Registration.)

**Section 2: Practice Information (A practice address is required for processing of your application.)**

Practice Name: Reliant Health Primary & Wellness Care

Practice Address: 6090 S. Fort Apache Rd Suite #: 140

City: Las Vegas State: NV Zip: 89148

Telephone: 702-202-0534 Fax: 702-952-9746 Email: info@reliantphysicians.com

**Section 3: Supervising Physician Information (NAC 639.272)**

Supervising Physician Name: Mit Pankaj Dave M.D.

Supervising Physician Practice Address: 1180 N. Town Center Drive Suite #: 100

City: Las Vegas State: NV Zip: 89144

Telephone: 702-202-2060 Fax: 866-536-1461 Email: info@reliantphysicians.com

| Section 4: Military Service (NRS 622.120) | Yes | No |
|---|---|---|
| 1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | ✔ | |
| 2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |
| 3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.) | | ✔ |

| Section 5: Federally Mandated Requirement (NRS 425.520, NRS 639.129) | Yes | No |
|---|---|---|
| 1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.) | | ✔ |
| 2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? | | ✔ |

| Section 6: Personal and Professional History | Yes | No |
|---|---|---|
| 1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license? | ✔ | |
| 2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state? | ✔ | |
| 3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? | ✔ | |
| 4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state? | ✔ | |

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # 1 . Provide all the following where applicable:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| | | | | |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| | | | | |
| **Reason/Charge** | | | | |
| | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| | | | | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

In 2004 I entered the inpatient professionals program at the Betty Ford Center a period of forty days. While I maintained sobriety for periods of time, I returned to inpatient care through the Las Vegas Recovery Center for twenty-eight days in September of 2019 and have continued to participate in aftercare since leaving that facility and continue to actively work on my recovery. I currently attend two to three AA meetings every week, work with a sponsor, and work the 12 steps of recovery. I also sponsor other men in the program and volunteer my time at meetings with various commitments. Additionally, I have been working with an excellent therapist for over three years now who specializes in drug and alcohol counseling, EMDR, and cognitive behavioral therapy.

In addition to the recovery activities discussed above, in November 2021 I began participating with the Professional Recovery Network (PRN) Program, oversee by Mark Chase, Program Director. I have signed a five year contract with PRN and am in full compliance with all the requirements of the contract. I attend weekly meetings with other medical practitioners and submit to random drug testing every month; all of which have been negative. The Nevada State Board of Medical Examiners is aware of my PRN contract and updates are regularly sent to that Board by Mr. Chase. Should you need any supporting documentation related to my participation with PRN please let me know and please feel free to contact Mr. Chase, his contact information is provided below.

Mark Chase, M.A., MBA, LCADC, Clinical Program Director, 702-335-9943, prnmark@pm.me

A Kuehl

Original Signature (electronic, copies or stamps not accepted)

07/16/2023

Date

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # 2 . Provide all the following where applicable:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| 06/21/2019 | 12/10/2020 | CA | Palm Springs | Riverside |

| Case # | Governing, licensing, Arresting Presiding Body/Agency/Court |
|---|---|
| INM1904850 | Superior Court of California, County of Riverside |

| Reason/Charge |
|---|
| Resisting or deterring officer |

| Plaintiff/Defendant/Claimant/Respondent | Lawsuit/Arbitration/Bankruptcy |
|---|---|
| Aaron Kuehl | N/A |

| Name of Business/Industry/Entity |
|---|
| N/A |

**Provide explanation below:**

I was arrested on June 21, 2019, in Palm Springs, CA for resisting or deterring a police officer. I was pulled over by Palm Springs Police Department officers after speeding through a yellow light at an intersection. There was a long wait for the police to come to my car, so I decided to get out of my vehicle and ask what was going on. The officers were very upset that I got out of the car and confronted me. We exchanged some words, and then I asked them to not touch me, but the police officer grabbed my arm and I tried to pull away from him. I was arrested and taken to Riverside County Jail for resisting or deterring a police officer. After my initial appearance in Riverside Superior Court (case no. INM1904850) my case was transferred to Military Diversion Court, because of my military service, and having served overseas. Upon my completion of all requirements of the Military Diversion Court the charges were ultimately dismissed in December 2020 and the matter closed.

A Kuehl

Original Signature (electronic, copies or stamps not accepted)

07/16/2023

Date

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # 3 . Provide all the following where applicable:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| 07/11/2002 | 05/16/2003 | CA | San Diego | San Diego |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| IE-2002-132677 | | Physician Assistant Committee Medical Board of California | | |
| **Reason/Charge** | | | | |
| Please see below | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| Aaron Kuehl | | | N/A | |
| **Name of Business/Industry/Entity** | | | | |
| N/A | | | | |

**Provide explanation below:**

In March 2003, I entered into a Stipulated Settlement with the Physician Assistant Committee (Committee) of the Medical Board of California which was effective May 16, 2003. The Stipulated Settlement resolved a disciplinary Accusation filed by the Committee in July 2002 which alleged I had stolen controlled substances (Soma and Vicodin) from my employer' s office supply; treating patients while impaired, and dishonest acts.

Pursuant to the terms of the Stipulated Settlement and Disciplinary Order, my physician assistant license was revoked; however the revocation was stayed and I was placed on seven years of probation. The terms of probation included a ninety-day suspension of my license, restrictions on my ability to prescribed controlled substances, a requirement that I enter into the California Diversion Program and submit to random drug and alcohol screens as requested and was required to abstain from alcohol and controlled substances or dangerous drugs for personal use, other than those prescribed by a practitioner. Additionally, I was subject to provisions related to required supervision by a physician and requirements related to my practice and was required to complete an ethics course.

I complied with the terms of my probation, including completion of the ethics course before relocating to Nevada prior to the completion of my probation and did not renew my license in 2004. As it has been more than five years since I last renewed my California license, my license I automatically cancelled and I would be required to reapply for licensure if I chose to return to the state of California to practice.

A Kuehl

Original Signature (electronic, copies or stamps not accepted)

07/16/2023

Date

**Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

**This is in response to Question # 4 . Provide all the following where applicable:**

| Date of Event/Arrest | Disposition Date | State | City | County |
|---|---|---|---|---|
| 07/11/2002 | 05/16/2003 | CA | San Diego | San Diego |
| **Case #** | | **Governing, licensing, Arresting Presiding Body/Agency/Court** | | |
| IE-2002-132677 | | Physician Assistant Committee Medical Board of California | | |
| **Reason/Charge** | | | | |
| Please see below | | | | |
| **Plaintiff/Defendant/Claimant/Respondent** | | | **Lawsuit/Arbitration/Bankruptcy** | |
| Aaron Kuehl | | | N/A | |
| **Name of Business/Industry/Entity** | | | | |
| | | | | |

**Provide explanation below:**

The action taken by the Physician Assistant Committee (Committee) of the Medical Board of California as described in the explanatory answer to Question #3 was taken in part for allegations of unlawful use or prescribing related to my diversion of controlled substances from my supervising physicians office in 2002.

A Kuehl

Original Signature (electronic, copies or stamps not accepted)

07/16/2023

Date

**I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.**

Aaron KuehL

Applicant Print Name (First, Last)

A Kuehl — 07/14/23

Original Signature (electronic, copies or stamps not accepted) — Date

**Required Supervising Physician's name and signature (NAC 639.272):**

MIR P DAVE, MD

Supervising Physician's Print Name (First, Last)

[signature] — 7/18/23

Original Signature (electronic, copies or stamps not accepted) — Date

Board Use Only: Date Processed: _____ Amount: 200- cc

Question #2

# RIVERSIDE SUPERIOR COURT

PUBLIC ACCESS

## Criminal Case Report

**Pay Ticket / Case Fine**

Send me an email when this case is updated (click here)

Print This Report

Purchase Documents for this Case

Close This Window

### Case INM1904850 - Defendants

| Seq | Defendant | Next Court Date | Status | Agency / DR Number | Arrest Date | Count 1 Charge | Violation Date |
|---|---|---|---|---|---|---|---|
| 1 | KUEHL, AARON HARRIS | | | PSPD 1906P4797 | 06/21/2019 | PC M69 | 06/21/2019 |
| | ALIAS: KEUHL, AARON H | | | | | | |

### Case INM1904850 - KUEHL, AARON HARRIS - Status

*Custody* **N/A**
*Filing Type* **Complaint**
*Filing Date* **07/31/2019**
*Ordered Bail* **$0.00**
*Posted Bail* **$0.00**
*D.A.* **Allison Roach**
*Defense* **DPD Barbara Plate**
*Next Action:*
*Deputy Report #:* **PSPD 1906P4797**

| Warrant | Type | Status | Issued | Affidavit |
|---|---|---|---|---|
| | | NONE | N/A | N/A |
| **Probation** | Type | | Granted | Expiration |
| | N/A | | N/A | N/A |
| **Sentence** | Convicted Date | | Fine and Penalty | Restitution Fine |
| | N/A | | | 0 |

### Case INM1904850 - KUEHL, AARON HARRIS - Charges

| Arrest Charges | | | | | | |
|---|---|---|---|---|---|---|
| Count | Charge | Severity | Description | Violation Date | Plea | Status |
| 1 | PC M69 | M | Resisting or Deterring Officer | 06/21/2019 | N/A | |
| **Filed Charges** | | | | | | |
| Count | Charge | Severity | Description | Violation Date | Plea | Status |

| | | | | | | |
|---|---|---|---|---|---|---|
| 1 | PC M69 | M | Resisting or Deterring Officer | 06/21/2019 | | DISMISSED |

## Case INM1904850 - KUEHL, AARON HARRIS - Probation

**Probation Has Not Been Granted On This Case For This Defendant.**

## Case INM1904850 - KUEHL, AARON HARRIS - Related Cases On Calendar

| Related Cases On Calendar |
|---|
| *This Defendant Does Not Have Any Other Cases With Future Hearings Scheduled.* |

## Case INM1904850 - KUEHL, AARON HARRIS - All of Defendant's Other Cases

| *Case Number* | *Filed Date* | *Charges* | *Next Hearing* | *Jurisdiction* | *Status* |
|---|---|---|---|---|---|
| ***This Defendant Does Not Have Any Other Reportable Cases.*** | | | | | |

## Case INM1904850 - KUEHL, AARON HARRIS - Actions & Minutes

| *Action Date* | *Action Text* | *Disposition* | *Hearing Type* |
|---|---|---|---|
| 12/10/2020 1:30 PM DEPT. RVC | MILITARY DIVERSION HEARING RE: PROGRESS/DISMISSAL PURSUANT TO PC 1001.80 | DISPOSED | |
| **Minutes** Print Minute Order | | | |
| 09/10/2020 1:30 PM DEPT. RVC | HEARING SET RE: STATUS ANGER MGMT CLASS | DISPOSED | |
| **Minutes** Print Minute Order | | | |
| 09/10/2020 1:30 PM DEPT. RVC | MILITARY DIVERSION HEARING RE: PROPGRESS PURSUANT TO PC 1001.80 | DISPOSED | |
| **Minutes** Print Minute Order | | | |
| 06/25/2020 | HEARING SET 06/25/2020 AT 13:30 FOR HS IS VACATED. | | |
| 06/25/2020 1:30 PM DEPT. RVC | HEARING SET RE: STATUS ANGER MGMT CLASS | VACATED | |
| 06/25/2020 1:30 PM DEPT. RVC | MILITARY DIVERSION HEARING RE: PROGRESS PURSUANT TO PC 1001.80 | DISPOSED | |
| **Minutes** Print Minute Order | | | |
| 06/16/2020 | NOTICE OF APPEARANCE INFORMATION FILED. | | |
| 05/22/2020 1:30 PM DEPT. RVC | HEARING SET RE: STATUS ANGER MGMT CLASS | DISPOSED | |
| **Minutes** Print Minute Order | | | |

| | | | |
|---|---|---|---|
| 05/14/2020 1:30 PM DEPT. RVC | MILITARY DIVERSION HEARING RE: PROGRESS PURSUANT TO PC 1001.80 | DISPOSED | |
| **Minutes** | Print Minute Order | | |
| 03/26/2020 1:30 PM DEPT. RVC | HEARING SET RE: STATUS ANGER MGMT CLASS | DISPOSED | |
| **Minutes** | Print Minute Order | | |
| 02/13/2020 1:30 PM DEPT. RVC | MILITARY DIVERSION HEARING RE: PROGRESS PURSUANT TO PC 1001.80 | DISPOSED | |
| **Minutes** | Print Minute Order | | |
| 02/13/2020 | VETERANS COURT PROGRESS REPORT FILED. | | |
| 12/13/2019 | REQUEST FOR MILITARY DIVERSION; ADVISAL AND WAIVER OF RIGHTS FILED. [RI-CR052] | | |
| 12/13/2019 | MILITARY DIVERSION PROGRESS HEARING PARTICIPANT FILED (CONFIDENTIAL) | | |
| 12/13/2019 | NOTICE OF BAIL BOND EXONERATION FILED. | | |
| 12/13/2019 8:30 AM DEPT. RVC | HEARING RE: MILITARY DIVERSION ELIGIBILITY | DISPOSED | |
| **Minutes** | Print Minute Order | | |
| 11/15/2019 8:30 AM DEPT. RVC | HEARING RE: MILITARY DIVERSION ELIGIBILITY | DISPOSED | |
| **Minutes** | Print Minute Order | | |
| 10/04/2019 | WAIVER OF DEFENDANT'S PERSONAL PRESENCE PURSUANT TO 977 PC FILED. | | |
| 10/04/2019 | DEFENDANT'S FINANCIAL STATEMENT AND NOTICE TO DEFENDANT FILED. (CONFIDENTIAL) | | |
| 10/04/2019 | REQUEST FOR CONTINUANCE PURSUANT TO PC 1050 FILED. | | |
| 10/04/2019 8:30 AM DEPT. RVC | HEARING RE: VETERANS COURT ELIGIBILITY | DISPOSED | |
| **Minutes** | Print Minute Order | | |
| 08/05/2019 8:30 AM DEPT. 2K | ARRAIGNMENT | DISPOSED | ARRAIGNMENT |
| **Minutes** | Print Minute Order | | |
| 08/01/2019 | RELEASED ON BOND. APPEARANCE DATE IS 08/05/2019. | | |
| 08/01/2019 | CASE DESIGNATION: VERTICAL. CASE ASSIGNED TO DEPT. 2K | | |
| 07/31/2019 | ELECTRONIC - DECLARATION IN SUPPORT OF ARREST | | |

| | | | |
|---|---|---|---|
| | WARRANT RECEIVED. | | |
| 07/31/2019 | ELECTRONIC - COMPLAINT FILED. | | |
| 06/25/2019 | BAIL BOND NO. FCS101987709 FILED. APPEARANCE DATE IS 08/05/2019. | | |
| 06/25/2019 | BAIL BOND NO. FCS101987709 IS TO BE ADDRESSED BY 06/22/2021, WHICH IS 2 YEARS FROM EFFECTIVE DATE 06/22/2019 (PC1304) | | |

## Case INM1904850 - KUEHL, AARON HARRIS - Fine Information

*Date To Pay:* **N/A** *First Payment: //*

*Prior NSF:* *Payment Amount:* **$0.00** *Last Payment: //*

| *Fine Number* | *Fine Type* | *Fine Description* | *Original Amount* | *Paid To Date* | *Current Due* |
|---|---|---|---|---|---|
| | | | | | |
| | | **Total:** | $0.00 | $0.00 | $0.00 |

Print This Report

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Questions #3 + #4



FILED
STATE OF CALIFORNIA
MEDICAL BOARD OF CALIFORNIA
SACRAMENTO July 11 2002
BY [signature] ANALYST

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Attorneys for Complainant

**BEFORE THE**
**PHYSICIAN ASSISTANT COMMITTEE**
**MEDICAL BOARD OF CALIFORNIA**
**DEPARTMENT OF CONSUMER AFFAIRS**
**STATE OF CALIFORNIA**

| | |
|---|---|
| In the Matter of the Accusation Against:<br><br>AARON H. KUEHL, P.A.<br>[redacted] Jewell Street, #[redacted]<br>San Diego, California 92109<br><br>Physician Assistant No. PA 14224<br><br>Respondent. | Case No. 1E-2002-132677<br><br>**ACCUSATION** |

Complainant alleges:

PARTIES

1. Richard L. Wallinder, Jr. (Complainant) brings this Accusation solely in his official capacity as the Executive Officer of the Physician Assistant Committee, Department of Consumer Affairs.

2. On or about January 6, 1998, the Physician Assistant Committee issued Physician Assistant No. PA 14224 to Aaron H. Kuehl, P.A. (Respondent). The Physician Assistant was in full force and effect at all times relevant to the charges brought herein and will expire on March 31, 2004, unless renewed.

///

JURISDICTION

3. This Accusation is brought before the Physician Assistant Committee, Medical Board of California (Committee), under the authority of the following sections of the Business and Professions Code (Code).

4. Section 3527 of the Code provides that the committee may order the denial of an application for, or the issuance subject to terms and conditions of, or the suspension or revocation of, or the imposition of probationary conditions upon a physician's assistant certificate for unprofessional conduct.

5. Section 125.3 of the Code states, in pertinent part, that the Committee may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

6. Section 2239 of the Code states

"(a) The use or prescribing for or administering to himself or herself, of any controlled substance; or the sue of any of the dangerous drugs specified in Section 4022, or of alcoholic beverages, to the extent, or in such a manner as to be dangerous or injurious to the licensee, or to any other person or to the public, or to the extent that such use impairs the ability of the licensee to practice medicine safely or more than one misdemeanor or any felony involving the use, consumption, or self-administration of any of the substances referred to in this section, or any combination thereof, constitutes unprofessional conduct . . . . "

7. Section 2280 of the Code states

"No licensee shall practice medicine while under the influence of any narcotic drug or alcohol to such an extent as to impair his or her ability to conduct the practice of medicine with safety to the public and his or her patients. Violation of this section constitutes unprofessional conduct and is a misdemeanor."

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8. Section 2234 (e) of the Code states "The commission of any act involving dishonesty or corruption which is substantially related to the qualifications, functions, or duties of a physician and surgeon" is unprofessional conduct."

9. Section 11173 of the Health and Safety Code states that "(a) no person shall obtain or attempt to obtain controlled substances, or procure the administration of or prescription for controlled substances, (1) by fraud, deceit, misrepresentation, or subterfuge; or (2) by the concealment of a material fact . . . . "

10. California Code of Regulations ("CCR"), Title 16, Section 1399.521 provides in pertinent part, "[i]n addition to the grounds set forth in section 3527, subdivision (a), of the [C]ode the [C]ommittee may deny, issue subject to terms and conditions, suspend, revoke, or place on probation a physician assistant for the following causes:

"(a) any violation of the State Medical Practice Act which would constitute unprofessional conduct for a physician and surgeon.

". . ."

11. Vicodin is a Schedule III controlled substance under Health and Safety Code section 11056(e). Soma (Carisoprodol) is a non-scheduled prescription drug indicated for the relief of acute, painful musculoskeletal conditions. Ultram (Tramadol hydrochloride) is a non-scheduled prescription drug used in the management of moderate to moderately severe pain.

FIRST CAUSE FOR DISCIPLINE

(Unlawful Use or Prescribing)

12. Respondent is subject to disciplinary action under section 2239 in that he unlawfully used Vicodin and Soma. The circumstances are as follows:

a. On or about December 16, 2001, respondent was hired by Dr. S. to be his physician assistant and provide pre and post-operative care, and to assist Dr. S during surgical procedures.

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b. On or about April 10, 2002, Dr. S., and his office manager spoke with respondent about the theft and use of drugs from the office supply. They also discussed with respondent his attendance problems, and the two occasions in which respondent passed out during his assisting in surgeries.

c. Respondent admitted taking Vicodin, Soma, and Ibuprofen from the office supply. He also admitted taking two Soma tablets on the morning of April 9, 2002.

d. Respondent also admitted taking a bottle of Vicodin and a bottle of Soma in January 2002, from the office supply cabinet.

e. On or about May 8, 2002, respondent provided the Medical Board with a urine sample. At the time of the sample respondent was asked whether he had taken any medications that day and he said "no".

f. On or about the results of the urinalysis were received. It tested positive for Ultram

13. Respondent unlawfully used controlled and dangerous drugs within the meaning of section 2239 by reason of, but not limited too, the following:

a. Paragraph 12 (a) through (f) is incorporated by reference as if fully set forth herein.

b. During his employment with Dr. S., respondent, on two different occasions, unlawfully took bottles of Vicodin and Soma from Dr. S.'s office supply.

SECOND CAUSE FOR DISCIPLINE

(Intoxicated While Treating Patient)

14. Respondent is subject to disciplinary action under section 2280 in that during the time of his employment with Dr. S. respondent took and ingested Vicodin and/or Soma, the effects of which caused him to be under intoxicated at a time when he was assisting Dr. S. in surgical procedures. Paragraph 12 (a) through (f) is incorporated by reference as if fully set forth herein.

THIRD CAUSE FOR DISCIPLINE

(Dishonest Acts)

15. Respondent is subject to disciplinary action under section 2234 (e) in that during the time of his employment with Dr. S. he committed dishonest acts which were substantially related to the qualifications, functions, or duties of a physician assistant by reasons of, but not limited too, the following:

a. Paragraph 12 (a) through (f) is incorporated by reference as if fully set forth herein.

b. Respondent stole bottles of Vicodin and Soma from the office supply of Dr. S, his physician supervisor.

c. Respondent lied to the Medical Board when he denied taking any medication at the time he gave his urine sample.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Physician Assistant Committee issue a decision:

1. Revoking or suspending Physician Assistant No. PA 14224, issued to Aaron H. Kuehl, P.A.;

2. Ordering Aaron H. Kuehl, P.A. to pay the Physician Assistant Committee the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

3. Taking such other and further action as deemed necessary and proper.

DATED: July 11, 2002

Richard L. Wallinder Jr.

RICHARD L. WALLINDER, JR.
Executive Officer
Physician Assistant Committee
Department of Consumer Affairs
State of California
Complainant

BEFORE THE
PHYSICIAN ASSISTANT COMMITTEE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

| | | |
|---|---|---|
| In the Matter of the Accusation Against: | ) | |
| AARON H. KUEHL, P.A. | ) | Case No: 1E-2002-132677 |
| Physician Assistant License Number PA-14224 | ) | |
| Respondent. | ) | |

## DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby accepted and adopted as the Decision and Order by the Physician Assistant Committee, Medical Board of California, Department of Consumer Affairs, State of California.

This Decision shall become effective at 5:00 p.m. on May 16, 2003

ORDERED April 16, 2003

PHYSICIAN ASSISTANT COMMITTEE

Robert Sachs, P.A., Chairperson

BILL LOCKYER, Attorney General
of the State of California
STEVEN H. ZEIGEN, State Bar No. 60225
Deputy Attorney General
California Department of Justice
110 West "A" Street, Suite 1100
San Diego, CA 92101

P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 645-2074
Facsimile: (619) 645-2061

Attorneys for Complainant

**BEFORE THE**
**PHYSICIAN ASSISTANT COMMITTEE**
**MEDICAL BOARD OF CALIFORNIA**
**DEPARTMENT OF CONSUMER AFFAIRS**
**STATE OF CALIFORNIA**

| | |
|---|---|
| In the Matter of the Accusation Against:<br><br>AARON H. KUEHL, P.A.<br>[redacted] Jewell Street, [redacted]<br>San Diego, CA 92109<br><br>Physician Assistant No. PA 14224<br>Respondent. | Case No. 1E-2002-132677<br><br>OAH No. L-2002100152<br><br>**STIPULATED SETTLEMENT AND DISCIPLINARY ORDER** |

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Richard L. Wallinder, Jr. (Complainant) is the Executive Officer of the Physician Assistant Committee. He brought this action solely in his official capacity and is represented in this matter by Bill Lockyer, Attorney General of the State of California, by Steven H. Zeigen, Deputy Attorney General.

2. Respondent Aaron H. Kuehl, P.A. (Respondent) is represented in this proceeding by attorney M. Gayle Askren, Esq., whose address is 1012 Park Place, Coronado, California 92118.

3. On or about January 6, 1998, the Physician Assistant Committee issued Physician Assistant License No. PA 14224 to Aaron H., Kuehl, P.A. (Respondent).

JURISDICTION

4. Accusation No. 1E-2002-132677 was filed before the Physician Assistant Committee (Committee) for the Medical Board of California, Department of Consumer Affairs, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on or about June 25, 2002. Respondent timely filed his Notice of Defense contesting the Accusation. A copy of Accusation No. 1E-2002-132677 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 1E-2002-132677. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

6. Respondent is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at his own expense; the right to confront and cross-examine the witnesses against him; the right to present evidence and to testify on his own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

8. Respondent admits the truth of each and every charge and allegation of paragraphs 12, 13, and 15 of the Accusation No. 1E-2002-132677.

9. Respondent agrees that his Physician Assistant License is subject to discipline and he shall be bound by the Physician Assistant Committee (Committee) 's

imposition of discipline as set forth in the Disciplinary Order below.

CONTINGENCY

10. This stipulation shall be subject to approval by the Physician Assistant Committee. Respondent understands and agrees that counsel for Complainant and the staff of the Physician Assistant Committee may communicate directly with the Committee regarding this stipulation and settlement, without notice to or participation by Respondent or his counsel. By signing the stipulation, Respondent understands and agrees that he may not withdraw his agreement or seek to rescind the stipulation prior to the time the Committee considers and acts upon it. If the Committee fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Committee shall not be disqualified from further action by having considered this matter.

11. The parties understand and agree that facsimile copies of this Stipulated Settlement and Disciplinary Order, including facsimile signatures thereto, shall have the same force and effect as the originals.

12. In consideration of the foregoing admissions and stipulations, the parties agree that the Committee may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

**DISCIPLINARY ORDER**

IT IS HEREBY ORDERED that Physician Assistant License No. PA 14224 issued to Respondent Aaron H. Kuehl, P.A. is revoked. However, the revocation is stayed and Respondent is placed on probation for seven (7) years on the following terms and conditions.

1. ACTUAL SUSPENSION As part of probation, respondent is suspended from the practice of medicine as a physician assistant for Ninety (90) days, beginning the effective date of this decision.

2. CONTROLLED DRUGS - TOTAL RESTRICTIONS Respondent shall not administer, order, transmit orally or in writing on a patient's record or hand to a patient or possess any controlled substances as defined in the California Uniform Controlled Substances

Act, except upon the order of a physician for whom respondent is acting as a physician assistant.

3. DRUGS - ABSTAIN FROM USE / EXEMPTION FOR PERSONAL USE Respondent shall abstain completely from the personal use or possession of controlled substances as defined in the California Uniform Controlled Substances Act, and dangerous drugs as defined by Section 4211 of the Business and Professions Code, or any drugs requiring a prescription.

Orders forbidding respondent from personal use or possession of controlled substances or dangerous drugs do not apply to medications lawfully prescribed to respondent for a bona fide illness or condition by another practitioner.

4. CONTROLLED DRUGS - MAINTAIN RECORD Respondent shall maintain a record of all controlled substances administered, transmitted orally or in writing on a patient's record or handed to a patient by the respondent during probation showing all the following: 1) the name and address of the patient, 2) the date, 3) the character and quantity of controlled substances involved, 4) the indications and diagnosis for which the controlled substance was furnished, and 5) the name of the supervising physician prescriber.

Respondent shall keep these records in a separate file or ledger, in chronological order, and shall make them available for inspection and copying by the Physician Assistant Committee or its designee, upon request and without charge.

5. ALCOHOL- ABSTAIN FROM USE Respondent shall abstain completely from the use of alcohol-containing products and beverages.

6. BIOLOGICAL FLUID TESTING Respondent shall immediately submit to biological fluid testing upon the request of the Physician Assistant Committee or its designee. The cost of biological fluid testing shall be borne by respondent.

7. DIVERSION PROGRAM Within 30 days of the effective date of this decision, respondent shall enroll and participate in the Physician Assistant Committee's Diversion Program until the committee or its designee determines that further treatment and rehabilitation is no longer necessary. Respondent shall participate in the program at his own expense. Quitting the program without permission or being expelled for cause shall constitute a

violation of probation by respondent.

8. ETHICS COURSE Within three months of the effective date of this decision, respondent shall submit to the committee or its designee for its prior approval a course in ethics, which respondent shall successfully complete during the first year of probation. Respondent shall participate in an ethics course at his own expense.

9. MONITORING / SUPERVISION Within 30 days from the expiration of respondent's ninety (90) day suspension from the practice of medicine as a physician assistant, respondent shall submit to the committee or its designee for its prior approval a plan of practice in which respondent's practice shall be monitored by an approved supervising physician responsible for patients treated by the physician assistant.

If the supervising physician/monitor resigns or is no longer available, respondent shall, within 15 days, move to have a new supervising physician/monitor appointed, through nomination by respondent and approval by the committee.

Respondent shall not practice as a physician assistant until the supervising physician is approved by the committee.

10. USE OF PROTOCOLS PROHIBITED Respondent is prohibited from using protocols when practicing as a physician assistant. All orders must be patient specific.

11. MAINTENANCE OF PATIENT MEDICAL RECORDS Respondent shall keep written medical records on all patient contacts (including all visits and phone calls).

All medical records originated by the respondent shall be reviewed, initialed, and dated daily by a supervising physician.

This condition shall be valid for three (3) years from the effective date of this decision.

12. ON-SITE SUPERVISION Respondent shall have at all times on-site or on call supervision by an approved supervising physician.

13. NOTIFICATION OF EMPLOYER AND SUPERVISING PHYSICIAN Respondent shall notify his current, and any subsequent employer and supervising physician(s), of his discipline and provide a copy of the Stipulation, Decision, and Order to each such

employer and supervising physician(s) during his period of probation, at the onset of that employment. Respondent shall ensure that each employer informs the Physician Assistant Examining Committee, or its agent, in writing within thirty (30) days, verifying that the employer and supervising physician(s) have been informed of this Stipulation and Order.

14. OBEY ALL LAWS Respondent shall obey all federal, state, and local laws, and all rules governing the practice of medicine as a physician assistant in California, and remain in full compliance with any court ordered criminal probation, payments, and other orders.

15. QUARTERLY REPORTS Respondent shall submit quarterly declarations under penalty of perjury on forms provided by the committee or its designee, stating whether there has been compliance with all the conditions of probation.

16. SURVEILLANCE PROGRAM Respondent shall comply with the committee's probation surveillance program.

17. INTERVIEW WITH MEDICAL CONSULTANT Respondent shall appear in person for interviews with the committee's medical or expert physician assistant consultant upon request at various intervals and with reasonable notice.

18. TOLLING FOR OUT-OF -STATE PRACTICE OR RESIDENCE The period of probation shall not run during the time respondent is residing or practicing outside the jurisdiction of California. If, during probation, respondent moves out of the jurisdiction of California to reside or practice elsewhere, including federal facilities, respondent is required to immediately notify the committee in writing of the date of departure and the date of return, if any.

19. INITIAL PROBATION INTERVIEW Respondent shall appear in person for an initial interview with a designee of the Physician Assistant Examining Committee within 90 days of the final decision. Respondent shall subject himself to an initial interview at a time and place determined by the committee or its designee.

20. UNANNOUNCED CLINICAL SITE VISIT At least once per calendar year, or more frequently as determined by the committee or its designee, unannounced clinical site visits shall be made by the committee or its designee to ensure that respondent is complying

with all terms and conditions of probation.

21. COMPLETION OF PROBATION Upon successful completion of probation as determined by the committee's executive officer, respondent's license will be fully restored.

22. VIOLATION OF PROBATION If respondent violates probation in any respect, the committee, after giving respondent notice and the opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If an accusation or petition to revoke probation is filed against respondent during probation, the committee shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final.

23. COST RECOVERY The respondent is hereby ordered to reimburse the Physician Assistant Examining Committee the amount of $4,299.00 within 90 days from the effective date of this decision for its investigative and prosecution costs. Failure to reimburse the committee's costs for its investigation and prosecution shall constitute a violation of the probation order, unless the committee agrees in writing to payment by an installment plan because of financial hardship. The filing of bankruptcy by the respondent shall not relieve the respondent of his responsibility to reimburse the committee for its costs.

24. VOLUNTARY LICENSE SURRENDER Following the effective date of this probation, if respondent ceases practicing due to retirement, health reasons, or is otherwise unable to satisfy the terms and conditions of probation, respondent may voluntarily tender his license to the committee. The committee reserves the right to evaluate the respondent's request and to exercise its discretion whether to grant the request, or to take any other action deemed appropriate and reasonable under the circumstances. Upon formal acceptance of the tendered license, respondent will no longer be subject to the terms and conditions of probation.

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## ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, M. Gayle Askren, Esq. . I understand the stipulation and the effect it will have on my Physician Assistant License No. P.A. 14224. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Physician Assistant Committee, Medical Board of California.

DATED: 3/3/2003, 2003.

AARON H. KUEHL, P.A.
Respondent

I have read and fully discussed with Respondent Aaron H. Kuehl, P.A. the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 3/3/2003, 2003.

M. GAYLE ASKREN, ESQ.
Attorney for Respondent

## ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Physician Assistant Committee, Medical Board of California of the Department of Consumer Affairs.

DATED: 3/3, 2003.

BILL LOCKYER, Attorney General
of the State of California

STEVEN H. ZEIGEN
Deputy Attorney General

Attorneys for Complainant

DOJ Docket Number: 03578160-SD2002AD0403
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SHZ:vc

# PRN Medical Professional Contract

The impaired Medical Professional Contract is a legal document that specifies the terms under which PRN agrees to counsel, aid, and monitor an impaired medical professional within the program. The purpose of this contract is to prevent any misunderstanding of the terms and the time specified. It is specifically designed to meet the needs of the individual. All provisions may not apply to every individual; however, all provisions will apply unless indicated explicitly for the omission.

**Provisions of the Contract**

1. I agree to the terms of this contract for a period of **five** years from the date of the agreement, with a reevaluation conducted annually.

2. I understand that all expenses connected with my treatment in the program are my responsibility. The PRN monthly fee is $200.00, which includes random drug screens, aftercare and peer support meetings, monthly reports to the Board, and one personal counseling session each month. Additional personal counseling sessions are billed at $70 per hour.

3. Based on our assessment, Detoxification Treatment is not required.

4. Based on our assessment, Residential Treatment is not required.

5. I agree to participate in the ***Aftercare In-Person*** meeting with PRN on the first Tuesday of each month and ***Peer Support Counseling*** each Wednesday of each month, held at 1800 hours. Participants may be excused only once with prior approval and may miss a maximum of two Peer Group Counseling meetings per year. After the third absence, the governing Nevada State Board will be notified of the event.

6. I will attend AA, CA, or NA weekly meetings, in addition to any aftercare requirements. Upon request, I will provide PRN monthly reports with a list of meetings I attended.

# PRN Medical Professional Contract

7. I realize that my recovery is my responsibility, and to get the most from the program, I must follow the suggested guidelines. Therefore, I will get a sponsor within the first 90 days of recovery, and I will work the twelve steps to the best of my ability.

8. I agree to meet with my sponsor weekly for the first 90 days, and a minimum of 2 times each month thereafter.

9. I agree to participate in a 90/90 program if I have not already completed one associated with my recovery program.

10. If the participant is not comfortable with AA, NA, or CA meetings, a written alternative and demonstrated, success may be submitted for consideration.

11. I agree to abstain from any mood-altering drugs, including alcohol, completely. If I am prescribed any opioids or benzodiazepines medication by a physician, I will notify PRN and provide a copy of the prescription for my file. During such time that I am taking the medication, I will check-in daily with PRN.

12. I agree to the payment of all financial obligations, including PRN monitoring fees.

13. I agree to identify a primary care physician.

14. At the discretion of PRN, I agree to be evaluated by a psychiatrist/psychologist for a thorough examination and recommendations for therapy at any time during my contract.

15. I agree to have no more than one individual counselor in addition to the PRN Clinical Director.

16. I agree to notify PRN within 72 hours of any changes to my address, phone number, employer, or work phone number.

# PRN Medical Professional Contract

17. I agree to submit to a urinalysis screening on a random basis, starting with one test per week and decreasing to one test per month with time. You must report within four hours of notification. In cases where you cannot leave your place of employment, you must report within two hours of your shift ending. If you reside outside of the Las Vegas area, alternative arrangements will be made.

18. I understand that the documentation of my progress will be kept confidential at PRN.

19. I understand that this contract is valid for five years from the date of my signature or until my termination from the PRN program, whichever is later.

20. I understand that I will be required to obtain an annual evaluation from my employer, which will become part of my confidential records at PRN.

21. I understand and agree that my failure to comply with any of this contract's provisions will result in notification to the governing Nevada State Board and my current employer. Furthermore, PRN is expressly authorized to furnish the State Board copies of this contract, medical records, drug screen results, and other records pertinent to my treatment and aftercare.

I HAVE READ AND UNDERSTAND ALL OF THE ABOVE INFORMATION:

A Kuehl — Signature

11-08-2021 — Date

Clinical Director

11-08-2021 — Date

# NSBME - Renewal Approved

From: noreply@nsbme.nv.us.thentiacloud.net

To: [redacted]

Date: Tuesday, May 2, 2023 at 03:33 PM PDT

Aaron KUEHL,

Your renewal has been approved.

Your license issued date is 2023/03/16

Your license expiration date is 2025/06/30

To obtain your wallet ID card, you must access the licensee portal to download the card. Wallet ID cards are accessible only via the licensee portal.

Thank you,

Nevada State Board of Medical Examiners

**Nevada State Board of Medical Examiners**
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559
Toll Free (in state) (888) 890-8210

# Aaron Harris KUEHL

| | |
|---|---|
| **License Number:** | PA2797 |
| **License Type:** | Physician Assistant |
| **License Status:** | Active-Conditions |
| **Initial License Date:** | Mar-16-2023 |
| **Expiration Date:** | Jun-30-2025 |
| **Public Address:** | 10248 Splendor Ridge Avenue |
| **Public City:** | Las Vegas |
| **Public State:** | Nevada |
| **Public ZIP Code:** | 89135 |
| **Public Country:** | United States |
| **Public Phone Number:** | (702) 835-2345 |
| **Credential:** | PA-C |

## Specialties

| Specialty |
|---|
| Physician Assistant |
| Physician Assistant |

## Education History

| Institution | Degree/Certificate | Date Enrolled | Date To |
|---|---|---|---|
| Oakes High School | High School Diploma | Aug-24-1987 | May-20-1990 |
| Augsburg University | Bachelor Degree | May-30-1995 | Aug-31-1997 |
| Augsburg University | Physician Assistant Degree | May-30-1995 | Aug-31-1997 |

## Board Actions

| Summary | Attachments |
|---|---|
| None. | |

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## Current Employment Status / Conditions / Restrictions on License / Prior Malpractice Claims

Summary

Attachments

None.

## Malpractice Information

Summary

Attachments

None.

## Supervised By

| Licensee | Relationship | Date of Association |
| --- | --- | --- |
| DAVE, Mit Pankaj | Primary Supervisor | Jul-13-2023 |

# 17

OPINION NO. 93-21 PHARMACY, BOARD OF; HOMEOPATHIC MEDICAL EXAMINERS, BOARD OF; DRUGS; CONTROLLED SUBSTANCES: Amendment of NRS 0.040 in 1985 allowed homeopathic physicians to be considered to be "physicians," but exclusively homeopathic practitioners may only possess, prescribe, dispense or administer those dangerous drugs and controlled substances in such manner and quantity as allowed by NRS 630A.040.

Carson City, September 20, 1993

Mr. Keith W. Macdonald, Executive Secretary, Nevada State Board of Pharmacy, 1201 Terminal Way, Suite 212, Reno, Nevada 89502

Dear Mr. Macdonald:

You have asked whether the amendment to NRS 0.040 made by the 1985 Legislature changes the letter opinion issued on January 7, 1985, such that an exclusively homeopathic physician may not prescribe, possess, dispense, and administer controlled substances and dangerous drugs. The brief answer to your question is that an exclusively homeopathic physician may prescribe a limited group of dangerous drugs (those that are "sarcodes") to patients and may possess and administer a limited group of dangerous drugs and controlled substances, all in compliance with the statutory criteria provided in NRS 630A.040.

## QUESTION

Did the amendment to NRS 0.040 enacted by the 1985 Legislature affect the letter opinion issued January 7, 1985, such that homeopathic physicians who are not also licensed as allopathic or osteopathic physicians may obtain a controlled substance registration or may prescribe, possess, or administer controlled substances and dangerous drugs?

## ANALYSIS

Prior to the 1985 legislative session, NRS 0.040 provided as follows:

> 1. Except as otherwise provided in subsection 2, as used in Nevada Revised Statutes, "physician" means a person who engages in the practice of medicine, including osteopathy.
> 2. The terms "physician," "osteopathic physician," "homeopathic physician" and "chiropractic physician" are used in chapters 630, 630A, 633, and 634 of NRS in the limited senses prescribed by those chapters respectively.

The 1985 Legislature left NRS 0.040(2) unchanged, but amended NRS 0.040(1) so that it now reads:

> Except as otherwise provided in subsection 2, "physician" means a person who engages in the practice of medicine, including osteopathy *and homeopathy*. [Emphasis added.]

This office rendered a letter opinion on January 7, 1985, regarding whether a homeopathic practitioner was a "physician" under NRS 0.040(1). The letter opinion was rendered prior to the amendment to NRS 0.040(1) and, in fact, precipitated the amendment. In the letter opinion, this

office drew two conclusions: (1) that a homeopathic physician was not a "physician" for the purposes of NRS chapters 453, 454, and 639; and (2) that a homeopathic physician who was also licensed in Nevada as an allopathic or osteopathic physician could write prescriptions for controlled substances and dangerous drugs, provided that the homeopathic physician did so only for legitimate allopathic or osteopathic treatment and not for homeopathic purposes.

The amendment of NRS 0.040(1) had the far-reaching effect of bringing homeopathic practitioners within the coverage of all the sections throughout the NRS in which reference is made to "physicians." The amendment of NRS 0.040(1) also changed the analysis of the January 7, 1985, letter opinion in the limited way that the question presented at that time, namely whether a homeopathic physician was a "physician" under NRS 0.040, must now be answered affirmatively. The amended and present version of NRS 0.040(1) clearly indicates that homeopathic physicians are "physicians" as that term may be used throughout the NRS. The inquiry does not end here, though.

Subsection (2) of NRS 0.040 refers inquiries regarding each of the specific practitioner groups in subsection (1) to each's specific practice act. As such, the answer to the specific question addressed in this opinion regarding the prescribing, possessing, and administering powers of exclusively homeopathic practitioners must be made by reference to various portions of the pharmacy laws and NRS chapter 630A, the practice act for homeopathic practitioners.

NRS 453.226(1) provides the general definition of those persons who must be registered with the board of pharmacy to distribute or dispense controlled substances:

> Every practitioner or other person who manufactures, *distributes or dispenses any controlled substance* within this state or who proposes to engage in the manufacture, *distribution or dispensing of any controlled substance* within this state shall obtain biennially a registration issued by the board in accordance with its regulations. [Emphasis added.]

A "practitioner" may administer controlled substances pursuant to NRS 453.375(1). A "practitioner," as defined in NRS 453.126, includes a "physician." Any person who manufactures, distributes or dispenses a controlled substance without prior registration may be punished by imprisonment of one to six years, may be fined not more than $2,000. NRS 453.232.

Similarly, NRS 454.213(1) allows a "practitioner" to possess and administer dangerous drugs, and NRS 454.215(3) allows a "practitioner" to dispense dangerous drugs. NRS 454.00958(1) defines a "practitioner" to include a "physician." Any person who furnishes dangerous drugs without the valid prescription of a practitioner may be imprisoned for one to six years, may be fined not more than $5,000, or both. NRS 454.221(1).

NRS 630A.040 specifically defines the pharmacopoeia of medicines available for use by homeopathic physicians as follows:

> "Homeopathic medicine" or "homeopathy" means a system of medicine employing substances of animal, vegetable, chemical or mineral origin, including nosodes and sarcodes, which are:
> 1. Given in micro-dosage, except that sarcodes may be given in macro-dosage;
> 2. Prepared according to homeopathic pharmacology by which the formulation of homeopathic preparations is accomplished by the methods of Hahnemannian dilution and succussion, magnetically energized geometric patterns, applicable in potencies above 30X as defined in the official Homeopathic Pharmacopoeia of the United States, or Korsakoffian; and
> 3. Prescribed by homeopathic physicians according to the medicines and dosages in the

Homeopathic Pharmacopoeia of the United States, in accordance with the principle that a substance which produces symptoms in a healthy person can eliminate those symptoms in an ill person, resulting in the elimination and prevention of illness utilizing classical methodology and noninvasive electrodiagnosis.

NRS 630A.090(4) clearly distinguishes homeopathic medicine from allopathic medicine and prohibits homeopathic physicians from practicing allopathic medicine: "This chapter does not authorize a homeopathic physician to practice medicine, including allopathic medicine, except as provided in NRS 630A.040." Additionally, pursuant to NRS 630A.230(2)(c), all homeopathic physicians must be licensed as allopathic or osteopathic physicians "in any state or country, the District of Columbia or a territory or possession of the United States." Thus homeopathic practitioners can be licensed exclusively as homeopathic physicians under NRS chapter 630A or can have dual licenses as homeopathic physicians and allopathic or osteopathic physicians.

In contrast to the narrow statutory scope of the practice of homeopathy, the definition of "practice of medicine" in NRS 630.020 is as follows:

1. To diagnose, treat, correct, prevent or prescribe for any human disease, ailment, injury, infirmity, deformity or other condition, physical or mental, by *any means or instrumentality*.
2. To apply principles or techniques of medical science in the diagnosis or the prevention of any such conditions.
3. To offer, undertake, attempt to do or hold oneself out as able to do any of the acts described in subsections 1 and 2.
4. To use in connection with a person's name the words or letters "M.D.," or any other title, word, letter or other designation intended to imply or designate him as a practitioner of medicine in any of its branches, *except in the manner authorized by NRS 630A.220*. [Emphasis added.]

The definition of "osteopathic medicine" is found in NRS 633.081 and provides:

"Osteopathic medicine" or "osteopathy" means the school of medicine which:
1. Utilizes full methods of diagnosis and treatment in physical and mental health and disease, including the prescribing and administering of drugs and biologicals of all kinds, operative surgery, obstetrics, radiological and other electromagnetic emission; and
2. Places emphasis on the interrelationship of the musculoskeletal system to all other body systems. [Emphasis added.]

The legislative intent from the above definitions is clear: homeopathy is a limited practice whereas allopathy and osteopathy are general. Allopaths may use "any means or instrumentality" in their practices. Osteopaths may use "full methods of diagnosis and treatment" in their practices. Homeopaths, on the other hand, are limited to using only those medications that satisfy NRS 630A.040 "in accordance with the principle that a substance which produces symptoms in a healthy person can eliminate those symptoms in an ill person, resulting in the elimination and prevention of illness utilizing classical methodology and noninvasive electrodiagnosis." Furthermore, an allopathic physician may not call himself a homeopathic physician. NRS 630.020(4). It is clear that the legislature intended homeopathy to be a distinct style of medicine with a specifically defined pharmacopoeia suited to the homeopathic practice of medicine.

The question of which drugs a homeopathic practitioner can prescribe, possess, or administer is answered by the three-part test in NRS 630A.040, namely that the drug must be (1) given in micro-dosage (except that sarcodes may be given in macro-dosage); (2) prepared according to homeopathic pharmacology; and (3) prescribed by homeopathic physicians according to the medicines and dosages in the Homeopathic Pharmacopoeia of the United States. Generally, the

dosages and forms of drugs maintained by Nevada pharmacies would not be in "micro-dosages," and would instead be in forms that would be deemed "macro-dosages" under NRS 630A.040. Thus NRS 630A.040 makes it clear that a homeopathic physician practicing homeopathically could not prescribe or administer the regular "macro-dosage" of any controlled substance or dangerous drug unless that drug were a "sarcode." No known allopathic drugs regularly stocked by Nevada pharmacists would be "sarcodes."[52]

A second question arises, though, as to whether a homeopathic practitioner may obtain and possess controlled substances and dangerous drugs for preparation of a homeopathic remedy therefrom. First, it seems unlikely that most of the regular stock of a Nevada pharmacy would qualify as the raw materials for the preparation of homeopathic remedies. Homeopathic remedies generally use organic materials and would not include the highly refined modern pharmaceuticals stocked by Nevada pharmacies.[53] Nonetheless, it may be that some pharmaceuticals, especially

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[52] A sarcode is defined by the latest edition of the Homeopathic Pharmacopoeia of the United States (June 1991) as follows:

> Sarcodes are homeopathic attenuations of wholesome organs, tissues, or metabolic factors obtained from healthy specimens.
>
> Sarcodes are prepared according to homeopathic specifications, provided the basic substance is *not* altered and the FINAL PRODUCT is *not* adulterated by any pathogen or other deleterious substance.
>
> Collection and preparation: refer to individual monograph.
>
> ATTENUATION PROCEDURE
>
> The freeze-dried organs, glands, or tissues are attenuated according to the specifications of Class F, and converted into liquid attenuations according to the specifications of Class H.

[53] Homeopathic remedies are identified by class. Following are the classes identified, taken from the Homeopathic Pharmacopeia of the United States (June 1991 updated):

> CLASS A - LIQUID ATTENUATIONS OF SOLUBLE SUBSTANCES
>
> Class A attenuations are prepared by dissolving one (1) part by weight of the soluble basic substance in a sufficient quantity of purified water or other appropriate menstruum, specified in the drug monograph, to produce ten (10) parts by volume of liquid attenuation which is designated 1X.
>
> CLASS B - LIQUID ATTENUATIONS OF SOLUBLE SUBSTANCES
>
> Class B liquid attenuations are prepared by dissolving one (1) part by weight of the soluble basic substance in a sufficient quantity of purified water or other appropriate menstruum, specified in the drug monograph, to produce 100 parts by volume of liquid attenuation which is designated 2X or 1CH.
>
> CLASS C - HOMOEOPATHIC TINCTURES OF BOTANICAL SUBSTANCES 1/10 (10%)
>
> Class C Tinctures, identified by the symbols "Tr.", Ø, or MT, are prepared by maceration or percolation from crude botanical substances, fresh or dried, by the dissolving action of an alcoholic vehicle.
>
> Class C tinctures are made to represent one (1) part by weight of dry crude material in ten (10) parts by volume of completed solution.
>
> CLASS D - HOMOEOPATHIC TINCTURES OF BOTANICAL SUBSTANCES 1/20 (5%)
>
> Class D Tinctures, identified by the symbols "Tr.", Ø, or MT, are prepared by maceration or percolation from crude botanical substances by the dissolving action of an alcoholic vehicle.
>
> Class D Tinctures are made to represent one (1) part by weight of dry crude material in 20 parts by volume of completed solution.
>
> CLASS E - HOMOEOPATHIC TINCTURES OF ZOOLOGICAL SUBSTANCES 1/20 (5%)
>
> Class E Tinctures are prepared by maceration from zoological substances, fresh or dried, by the dissolving action of an alcoholic vehicle.
>
> Class E Tinctures are made to represent one (1) part by weight of the crude material in 20 parts by weight of completed solution.
>
> CLASS F - TRITURATIONS OF SOLID SUBSTANCES
>
> Class F triturations of solid substances are prepared by triturating one (1) part by weight of the dry crude substance with nine (9) parts of

some controlled substances, may be stocked or available through Nevada pharmacies. For example, the monographs for homeopathic remedies include the following remedies that would be made from controlled substances: *anhalonium lewinii* (peyote), *cannabis indica/cannibis sativa* (marijuana), *cocainum* (cocaine), *cocainum muriaticum* (cocaine hydrochloride), *codeinum* (codeine), *datura arborea/datura metel* (datura), *morphinum* (morphine), *morphinum muriaticum* (morphine hydrochloride), and *opium* (opium). Additionally, it may be that some homeopathic remedies are fashioned from currently available dangerous drugs.

It is clear, therefore, that a homeopathic physician practicing homeopathically could legally obtain, possess, and administer some dangerous drugs and controlled substances for the manufacture of homeopathic remedies. Additionally, a homeopathic physician may also prescribe those dangerous drugs and controlled substances allowed by NRS 630A.040, but as a practical matter it is unlikely that any Nevada pharmacies stock dangerous drugs or controlled substances in homeopathic dosages or know how to prepare homeopathic remedies according to homeopathic methodology. To
possess controlled substances, the homeopathic practitioner would be required to obtain a registration with the Drug Enforcement Administration (DEA) and a registration with the Nevada Board of Pharmacy pursuant to NRS 453.226. Additionally, any order for a controlled substance in Schedules I and II would need to be via a DEA Form 222; any order for other controlled substances would need to be via a valid order form, and all record-keeping, storage, and security statutes and regulations would also be applicable.

Of course, possession and administration of the controlled substances and dangerous drugs obtained by a homeopathic practitioner must also comply with the terms of NRS 630A.040. Administration of a controlled substance or dangerous drug in contravention to the dictates of NRS

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Lactose, U.S.P., to make a 10% (1/10) trituration, which is designated 1X.

CLASS G - TRITURATION OF INSOLUBLE LIQUID SUBSTANCES

Class G triturations are prepared by triturating one (1) part by weight of insoluble liquid substance with sufficient Lactose, U.S.P., to produce a 10% (1/10) mixture by weight, which is designated the 1X trituration.

CLASS H - CONVERSION OF TRITURATIONS OF INSOLUBLE BASIC SUBSTANCES INTO LIQUID ATTENUATIONS

Class H conversions of triturations of insoluble basic substances into liquid attenuations are prepared by succussine on (1) part of the lowest soluble trituration of the substance (usually 6X) with sufficient distilled water or other appropriate menstruum to produce the next higher attenuation.

CLASS I - NOSODES

Nosodes are homeopathic attenuations of: pathological organs or tissues; causative agents such as bacteria, fungi, ova, parasites, virus particles, and yeast; disease products; excretions or secretions.

CLASS J - ALLERSODES

Allersodes are homeopathic attenuations of antigens, i.e., substances which, under suitable conditions, can induce the formation of antibodies. Antigens include toxins, ferments, percipitinogens, agglutinogens, opsonogens, lysogens, venins, agglutinins, complements, opsonins, amboceptors, precipitins, and most native proteins.

CLASS K - ISODES

Isodes, sometimes called Detoxodes, are homeopathic attenuations of botanical, zoological, or chemical substances, including drugs, excipients, or binders, which have been ingested or otherwise absorbed by the body and are believed to have produced a disease or disorder which interferes with homeostasis.

CLASS L - SARCODES

Sarcodes are homeopathic attenuations of wholesome organs, tissues, or metabolic factors obtained from healthy specimens.

630A.040 would subject a homeopathic practitioner to discipline by the Board of Homeopathic Examiners pursuant to NRS 630A.370(3) and (5), and to discipline by the Board of Pharmacy pursuant to NRS 453.241.

We suggest that representatives from the Boards of Pharmacy and Homeopathy meet to develop a comprehensive pharmacopoeia of drugs that Nevada pharmacists could provide to homeopathic practitioners or their patients that could be circulated among the members of the two professions. The pharmacopoeia should include at least the following categories: (1) those dangerous drugs that are "sarcodes" and could be prescribed by the homeopathic practitioner to be filled at a Nevada pharmacy; (2) those controlled substances that are in Schedules I and II that could be ordered by homeopathic practitioners from Nevada pharmacies for the manufacture of homeopathic remedies; (3) those controlled substances in Schedules III, IV, and V that could be ordered by homeopathic practitioners from Nevada pharmacies for the manufacture of homeopathic remedies; and (4) those dangerous drugs that could be ordered by homeopathic practitioners from Nevada pharmacies for the manufacture of homeopathic remedies.

The second conclusion contained in the letter opinion of January 7, 1985, remains essentially unchanged; namely that a homeopathic physician who is also licensed in Nevada as an allopathic or osteopathic physician may write prescriptions for controlled substances for allopathic or osteopathic, not homeopathic, purposes. NRS 453.381(1), the statute that is the basis of this part of the letter opinion, has not been changed in the interim since 1985. Similarly, a dangerous drug cannot legally be prescribed by a homeopathic physician except for allopathic or osteopathic, not homeopathic, purposes. *See* NRS 454.211, NRS 454.221.

Of course, the dually-licensed practitioner could also prescribe, obtain, possess, and administer those dangerous drugs and controlled substances for homeopathic purposes according to the homeopathic method as has already been discussed. In other words, when a dually-licensed practitioner is practicing allopathically or osteopathically, he could prescribe any dangerous drug or controlled substance, but when he is practicing homeopathically, he can only avail himself of the more narrow homeopathic pharmacopoeia of dangerous drugs and controlled substances.

## CONCLUSION

The 1985 amendment to NRS 0.040 authorizes exclusively homeopathic physicians to possess, dispense, or administer those controlled substances and dangerous drugs that are recognized by the Homeopathic Pharmacopoeia of the United States and otherwise comply with NRS 630A.040. To possess, dispense, or administer any controlled substances, a homeopathic physician must obtain a federal DEA registration and a Nevada controlled substances registration. Homeopathic physicians who are also licensed in Nevada as allopathic or osteopathic physicians, in addition to the limited abilities to possess, dispense, administer, and prescribe certain dangerous drugs and controlled substances according to homeopathic practice, may also possess, dispense, prescribe, or administer controlled substances and dangerous drugs as appropriate and necessary to their allopathic or osteopathic practices.

Sincerely,

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Attorney General

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1. When practicing one of the alternative therapies expressly authorized by A.B. 286 and defined in R213-97, homeopathic physicians may prescribe:

(a) Any controlled substance listed in schedule I, II, III, IV or V as set forth in chapter 453 of NRS, so long as both administration and dosage are medically appropriate according to the standards applicable to that alternative therapy, except that a homeopathic physician may not prescribe "narcotic drugs and opiates that are listed as schedule II controlled substances pursuant to chapter 453 of NRS, except as those substances may be described for use in the official Homeopathic Pharmacopoeia of the United States." (R213-97.)

(b) Any dangerous drug that is defined in chapter 454 of NRS so long as both administration and dosage are medically appropriate according to the standards applicable to that alternative therapy.

(c) Any other allopathic drug available by prescription so long as both administration and dosage are medically appropriate according to the standards applicable to that alternative therapy.

22-008 NV Leg. Counsel authorized homeopathic prescrip.

January 31, 2000

Senator Ann O'Connell
7225 Montecito Circle
Las Vegas, Nevada 89120-3118

Dear Senator O'Connell:

You have asked this office to address three questions relating to the practice of homeopathy in this state. Your questions arise from the interaction between Assembly Bill No. 286 of the 1997 Legislature, which amended the scope of homeopathic practice, the regulation adopted pursuant to that bill by the Board of Homeopathic Medical Examiners, and the February 11, 1999, opinion of the Attorney General which declared that regulation invalid. Specifically, you have asked (1) whether the Attorney General's opinion invalidating the regulation is correct; (2) whether the regulation is effective and valid, and if so, what authority homeopathic physicians possess to prescribe medications, including drugs, controlled substances and dangerous drugs; and (3) whether the authority to write prescriptions granted by this regulation is in conformity with the intent of the Legislature in enacting A.B. 286. The complexity of these issues makes it necessary to provide a significant amount of background information. After providing this information, we will answer each of your questions separately.

## I. Background

### A. Homeopathy in Nevada: 1983 to 1997

The licensed practice of homeopathy in this state began in 1983 when the Legislature authorized the practice and established the Board of Homeopathic Medical Examiners (Homeopathic Board) to regulate and license the practice. At that time, the Legislature defined homeopathy as a:

> [S]ystem of medicine employing substances of animal, vegetable, chemical or mineral origin [most of which are g]iven in micro-dosage ... and [p]repared according to homeopathic pharmacology by which the formulation of homeopathic preparations is accomplished by ... dilution ... and which is] in accordance with the principle that a substance which produces symptoms in a healthy person can eliminate those symptoms in an ill person, resulting in the elimination and prevention of illness utilizing classical methodology ...

(Section 5 of chapter 524, Statutes of Nevada 1983, at page 1479.)[1] To obtain a license as a homeopathic physician, an applicant must have graduated from either a conventional, that is, "allopathic," medical school or a school osteopathy and must have been licensed to practice allopathic or osteopathic medicine in some state, district, territory or possession of the United States or in a foreign country. (NRS 630A.230.) In 1983, as at present, it was possible, although not necessary, for a licensed homeopathic physician also to be

[1] This definition also included the use of "noninvasive electrodiagnosis," even though it is unlikely that this represented part of "classical" or traditional homeopathy.

licensed to practice conventional allopathic or osteopathic medicine.[2] Thus, while every homeopathic physician must have received training in allopathic or osteopathic medicine, each homeopathic physician may choose whether to continue to practice both forms of medicine, in which case he must be "dually-licensed," or to choose to practice homeopathy exclusively, in which case he need only be "singly-licensed." The 1983 statute did not clearly establish the scope of the authority to write prescriptions that a license to practice homeopathic medicine conferred on its holder. On the one hand, the statutory definition had authorized homeopathic physicians to use "chemical" substances. On the other hand, however, the existing statutory scheme applicable to prescription medicines suggested that homeopathic physicians lacked the authority to write prescriptions. It authorized "physicians" to prescribe drugs, but defined that term in a manner that excluded homeopathic physicians. (NRS 0.040 (1983.)) On January 7, 1985, the Attorney General issued an "informal opinion" advising that a singly-licensed homeopathic physician could not "prescribe, possess, dispense, [or] administer controlled substances and dangerous drugs." (1993 Nev. Op. Att'y Gen. 131, September 20, 1993 (A.G.O. 93-21).) Apparently, this informal opinion precipitated an amendment of NRS 0.040 at the next session of the Legislature. (*Id.*) The Legislature expanded the definition of "physician" expressly to include homeopathic physicians wherever "physician" was used in the NRS. (Section 5 of chapter 82, Statutes of Nevada 1985, at page 221.) This included those laws that conferred the authority to write prescriptions for pharmaceutical medicines or drugs generally, as well as for controlled substances and dangerous drugs. (Chapters 639, 453 and 454 of NRS.) It is not clear whether homeopathic physicians, or others, regarding this statute as conferring *carte blanche* authority on homeopathic physicians to prescribe allopathic drugs, but, at the next session in 1987, the Legislature imposed an explicit limitation on the authority of homeopathic physicians to write prescriptions. The Legislature amended the definition of homeopathy to make it plain that homeopathic physicians could only prescribe substances "according to the medicines and dosages in the Homeopathic Pharmacopoeia of the United States." (Section 10 of chapter 775, Statutes of Nevada 1987, at page 2056.)

In the fall of 1993, the Attorney General was asked to provide an opinion on the then present scope of homeopathic practice. Te Attorney General concluded that part of the 1985 informal opinion had been overtaken by circumstances and was no longer valid. She stated that "[i]t is clear . . . that a homeopathic physician practicing homeopathically [can] legally obtain, possess, and administer some dangerous drugs and controlled substances for the manufacture of homeopathic remedies." (1993 Nev. Op. Att'y Gen. 131, September 20, 1993.) (Emphasis added) In other words, a physician, practicing under his homeopathic license, could prescribe any medication, including allopathic medicines, controlled substances, and dangerous drugs, so long as it was found in the Homeopathic Pharmacopoeia and providing that he prescribed it in the dosages also

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[2] Both osteopathic and allopathic physicians are licensed and regulated by the State Board of Medical examiners (Medical Board). Moreover, doctors osteopathy have the same authority to prescribe allopathic prescription drugs, controlled substances and dangerous drugs as do doctors of medicine. For the remainder of this memo, therefore, when speaking of the authority to write prescriptions, we will use "allopathic" as inclusive of "osteopathic," except when it is necessary to distinguish between the two practices.

found there. This might include the authority to prescribe many allopathic drugs, but it almost certainly did not include the authority to prescribe such drugs in allopathic doses. Rather, the Attorney Gene3ral concluded that a homeopathic physician might write a prescription for one pill of an allopathic drug if he did so for the purpose of obtaining it to use in preparing a homeopathic medicine in which the dose of the controlled substance actually administered to the patient would be so diluted that it would conform to homeopathic standards. This interpretation seems to have been accepted by the homeopathic, allopathic and pharmaceutical communities. It is sometimes referred to as the "one-pill rule" and it covers the "micro-dosage" portion of the authority of a homeopathic physician to write prescriptions. The Attorney General also concluded that homeopathic physicians possessed a limited power to prescribe administer certain substances in "macro-dosages," but that these substances, called "sarcodes," were unlikely to be a part of the stock of conventional or allopathic drugs regularly stocked by pharmacists in this state.[3]

In the same 1993 opinion, however, the Attorney General formally adopted one of the conclusions endorsed by the earlier (1985) informal opinion. This was the conclusion that a physician who is dually licensed as both a homeopathic physician and as an allopathic (or osteopathic) physician could not use the authority to write prescriptions granted by his allopathic license to practice homeopathy. In other words, "when a dually-licensed practitioner is practicing allopathically or osteopathically, he can prescribe any dangerous drug or controlled substance, but when he is practicing homeopathically, he can only avail himself of the more narrow homeopathic pharmacopoeia . . . "(1993 Nev. Op. Att'y Gen. 131.) This restriction on the scope of practice, in conjunction with the "one-pill rule" (as modified by the exception for sarcodes), represents the *status quo ante*. Together, they constitute the background against which the subsequent legislation and regulation must be viewed.

### B. Assembly Bill No. 286 of the 1997 Legislature

In 1997, the Nevada Association of Homeopathic Physicians offered a bill to expand the scope of the licensed practice of homeopathy and to repeal the "one-pill rule." The homeopathic community believed that since all licensed homeopathic physicians had received allopathic (or osteopathic) training and had satisfied, in some state or country, the requirements to prescribe allopathic drugs in allopathic doses, they should be allowed to do so in Nevada as well. Assembly Bill No. 286 of the 1997 Legislature (A.B. 286), as introduced, employed three statutory mechanisms to bring this about. First, it eliminated the language in NRS 630A.040 that limited the authority of homeopathic physicians to write prescriptions to the substances and dosages found in the Homeopathic Pharmacopoeia. Second, it increased the Homeopathic Board's power over licensing to

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[3] According to the 1991 edition of the Homeopathic Pharmacopoeia of the United States, sarcodes are "homeopathic attenuations of wholesome organs, tissues, or metabolic factors obtained from healthy specimens . . . prepared according to homeopathic specifications [in which] the basic substance is not altered and the FINAL PRODUCT is not adulterated by any pathogen or other deleterious substance." The Attorney General concluded, "No known allopathic drugs regularly stocked by Nevada pharmacists would be 'sarcodes.'" (1993 Nev. Op. Att'y Gen. 131, September 20, 1993.)

permit the Board to determine on a case-by-case basis, "which allopathic pharmaceuticals and controlled substances, if any, the homeopathic physician or advanced practitioner of homeopathy may prescribe in conventional allopathic dosages." (Subsection 4 of section 1 of A.B. 286, as introduced). The Board was to base its decisions on an evaluation of each licensee's pharmacological expertise. Thus, if the Board was satisfied that an applicant for homeopathic licensure was as qualified to prescribe allopathic medicines in allopathic dosages as medical doctors licensed by the Medical Board, the Homeopathic Board would confer on him a license with equivalent authority. If it evaluated his pharmaceutical knowledge less favorably, it would issue a license that specified the particular allopathic drugs he was authorized to prescribe, or it could grant him a license that expressly disqualified him from prescribing conventional doses of any allopathic drug. Third, A.B. 286 expanded the definition of homeopathy to include the practice of "pharmaceutical medicine." Although this term was never defined with precision, it appears plain that it was intended to encompass the routine prescription of allopathic drugs in allopathic doses. (*See* Testimony of Robert F. Martin, Testimony of Michael J. Fischer, Hearing, Assembly Committee on Commerce, March 31, 1997.) One of the witnesses at the hearing before the Assembly Committee on Commerce provided the following example of what the supporters of A.B. 286 hoped to accomplish. Because relatively few states license homeopathic medicine, the practice of homeopathic physicians in this state includes the treatment of nonresidents who have traveled here for the express purpose of taking a course of homeopathic treatment. If, while undergoing this treatment, the patient manifested a disease that was easily treatable with simple antibiotics, for example, a strept throat, the supporters of A.B. 286 wished singly-licensed homeopathic physicians to have sufficient authority to write a prescription for the patient without having to refer him to an allopathically-licensed physician to obtain the antibiotic. (*See* Testimony of F. Fuller Royal, Testimony of Robert F. Martin, Hearing, Assembly Committee on Commerce, March 31, 1997.)

Besides this expansion in the authority to prescribe conventional allopathic medicines, the supporters of A.B. 286 hoped to expand the scope of homeopathic practice beyond its traditional or classical limits and to include what one witness called "complex homeopathy," but which might more accurately be described as a license for the practice of specific forms of alternative medicine. (Testimony of Robert F. Martin, Hearing, Assembly Committee on Commerce, March 31, 1997.) To accomplish this, the sponsors of A.B. 286 proposed amending the definition of homeopathy to include, in addition to the "non-invasive electrodiagnosis" that had formed part of the 1983 definition, the following alternative practice areas:

> [C]ell therapy, neural therapy, herbal therapy, neuromuscular integration, orthomolecular therapy, nutrition, intravenous infusion, [and] chelation therapy . . .[4]

(*See* A.B. 286, as introduced). None of these therapies fit within the traditional or

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[4] This clause also contained the expansion of homeopathy to include the practice of "pharmaceutical medicine," discussed above.

"classical," non-statutory definition of homeopathy. The president of the Homeopathic Board testified that "when [A.B. 286] talks about neural therapy, you are not talking about homeopathy. When it talks about orthomolecular therapy and herbalist medications, you're not talking about homeopathy." (Testimony of F. Fuller Royal, Minutes, Legislative Commission, December 18, 1998.) He also stated that there was "no such thing" as homeopathic neuromuscular integration and that the purpose of enumerating those additional therapies had been to "expand the practice of homeopathy." (Testimony of F. Fuller Royal, Minutes, Legislative Commission Meeting, June 26, 1998.) Consequently, because none of these alternative therapies constituted part of homeopathy as traditionally or classically conceived, A.B. 286 deliberately did not subject those therapies to the earlier limitations imposed on classical homeopathy. Thus, the medications that a homeopathic physician might prescribe under the therapies need not be selected in conformity with the fundamental homeopathic principle that a substance that would make a healthy person ill would, if diluted correctly, make an ill person healthy. Similarly, the authority of a homeopathic physician to write a prescription, when practicing one of these alternative therapies, was not limited to the substances or dosages that were found in the Homeopathic Pharmacopoeia.

At the hearing on the bill before the Assembly Committee on Commerce, both supporters and opponents agreed that the net effect of all these provisions would be to

significantly expand the ability of singly-licensed homeopathic physicians to practice allopathic medicine. Opponents of A.B. 286 objected to this expansion with an intensity that, apparently, would have been sufficient to prevent the entire bill from emerging from the Assembly Commerce Committee. Both the Chairman of that committee and another member recall informing the lobbyist for the homeopathic physicians that A.B. 286 would not pass unless certain objectionable elements were removed. Both legislators also recall that the lobbyist agreed to an amendment removing them. (*See* Comments of Assemblyman Richard Perkins, Comments of Assemblywoman Barbara E. Buckley, Minutes, Legislative Commission, June 28 and December 18, 1998.)

A.B. 286, as amended, considerably enhanced the power of the Homeopathic Board to regulate its own practitioners, but did not contain the language that would have authorized that board to "determine which allopathic pharmaceuticals and controlled substances, if any, the homeopathic physician . . . may prescribe in conventional allopathic dosages." Similarly, while the Assembly Committee on Commerce had accepted the Homeopathic Board's draft language establishing its right to discipline its own members, the committee amended that provision by adding an explicit declaration that if the conduct of a homeopathic physician concerned a practice that was within the jurisdiction of another licensing board, the Homeopathic Board was required to forward the complaint to the appropriate board for action. (See A.B. 286, First Reprint). Finally, the Committee edited the list of proposed alternative therapies. As previously mentioned, the Committee eliminated the general power to prescribe allopathic drugs in allopathic doses by removing the phrase "pharmaceutical medicine" from the list of alternative therapies. In its initial consideration of amendments to the bill, the committee retained the terms "intravenous infusion and chelation therapy." (See Exhibit C, Attachment B,

Minutes, Assembly Committee on Commerce, May 5, 1997.) These two terms, however, were also subsequently removed.[5] (*See* Floor Minutes of the Assembly Committee on Commerce, June 29, 1997, *Assembly Journal*, June 29, 1997, pp. 1777-78.)

With these changes in place, the Medical Board and State Board of Pharmacy (Pharmacy Board) withdrew their opposition to the legislation. The hearing on the amended bill before the Senate Committee on Commerce and Labor was relatively brief as there was no substantive opposition. One erstwhile opponent testified that in its present form the bill was "innocuous." (Testimony of Robert Barengo, Hearing, Senate Committee on Commerce and Labor, July 3, 1997.) However, the chairman of that committee recalls being informed that the terms "chelation therapy," "intravenous infusion," and pharmaceutical medicine" had been removed solely to eliminate redundancy or surplus language. He understood that it was agreed by all parties that those therapies were authorized by virtue of the remaining terms. For that reason alone, he recalls, the Senate committee did not conduct full hearings on the bill. (*See* Comments of Senator Randolph J. Townsend, Minutes, Legislative Commission, June 26, 1998; *see* also Comments of Senator Mark James, Minutes, Legislative Commission, December 18, 1998.)

Despite what now appears as an obvious difference in understanding between certain members of the Senate with some of their colleagues in the Assembly, there is nothing to suggest that members of either house were aware of these differences when they voted unanimously in favor of the amended bill. Although the new alternative therapies were each listed in the bill, they were not defined. Consequently, the Homeopathic Board attempted to supply these definitions by regulation.

### C. The Regulation and the Legislative Commission

The Homeopathic Board adopted its first set of proposed definitions on May 5, 1998, after conducting the required workshop0s and public hearings. The Legal Division of the Legislative Counsel Bureau assigned the proposed regulation the file number R213-97. The Medical and Pharmacy Boards participated in the hearings and, therefore, had early notice of the proposed definitions. The bulk of the definitions excited no controversy, but the representatives of the allopathic community insisted that in its definitions of two of the alternative therapies---orthomolecular medicine and neural therapy---the Homeopathic Board had exceeded its statutory authority. As originally submitted, the regulation defined "orthomolecular medicine" to include "[t]he prescription of . . . pharmaceutical medicines, [and] the intravenous infusion of various substances, including . . . pharmaceutical medications [and] chelating agents . . ." The regulation also defined "neural medicine" to mean the "injection of local anesthetics . . . medicinal or pharmaceutical substances . . ." The allopathic physicians objected that the definitions purported to permit homeopathic physicians to prescribe pharmaceutical "medicines," "medications," and "substances" when the authorization to practice

[5] These two terms will be discussed in greater detail in our response to your third question.

"pharmaceutical medicine" had been expressly removed by the Assembly Committee on Commerce. The same objection applied to the term "intravenous infusion" and the practice of chelation.

The Legal Division of the Legislative Counsel Bureau notified the Homeopathic Board of these objections, but the Homeopathic Board chose not to revise its regulation at that time. Consequently, when R213-97 was submitted to the Legislative Commission for approval at its June 26, 1998, meeting, representatives of the Homeopathic and Medical boards were on hand to present their arguments to the Commission. Under NRS 233B.067, the Commission has the authority to object to a regulation on two bases:

1. The regulation does not conform to statutory authority; or
2. The regulation does not carry out legislative intent.

The Commission heard extensive testimony and considered the matter at length. The majority of the testimony turned on the enhanced authority of homeopathic physicians to write prescriptions that were perceived to be found in the references to "pharmaceutical medicines," "pharmaceutical medications" and "pharmaceutical substances" in light of the Assembly amendment's removal of the term "pharmaceutical medicine" from A.B. 286. In particular, opponents objected---as they had at the hearing before the Assembly Committee on Commerce---to any expansion in the power of singly-licensed homeopathic physicians to prescribe allopathic dosages of controlled substances, including narcotics, and dangerous drugs. The Commission concluded that, assuming that the definitions selected by the Homeopathic Board and incorporated into the regulation were in accordance with authoritative sources in the field of alternative medicine, the regulation was within that board's statutory grant of authority. Nevertheless, the Commission voted to object to the regulation on the ground that the increased authority it conferred on homeopathic physicians to prescribe allopathic drugs in allopathic doses violated the legislative intent behind A.B. 286. (*See* Minutes, Legislative Commission Meeting, June 26, 1998.) Accordingly, the Director of the Legislative Counsel Bureau returned the regulation to the Homeopathic Board with a note of the Commission's objections. (*See* letter from Lorne J. Malkiewich to F. Fuller Royal, June 30, 1998.)

In accordance with the procedures set forth in NRS 233B.0675, the Homeopathic Board revised R213-97. The revised regulation replaced the terms "pharmaceutical medicines," "pharmaceutical medications," and "pharmaceutical substances," with a single term, "pharmaceutical preparations."[6] This term was then expressly limited to make plain that it did "not include narcotic drugs or opiates that are listed as schedule II controlled substances pursuant to chapter 453 of NRS, except as those substances may be described for use in the official Homeopathic Pharmacopoeia of the United States."

The revised regulation was resubmitted to the Legislative Commission for review

[6] The revised regulation also eliminated the term "local anesthetics" from the definition of neural therapy on the ground that such substances were included in the broader category of "pharmaceutical preparations."

at its December 18, 1998, meeting. Once again, the Commission heard extended testimony both for and against the regulation. The witness for the Homeopathic Board contended that inasmuch as the primary objection to the earlier regulation had been the expansion in the authority of homeopathic physicians to prescribe narcotics or other controlled substances in allopathic doses, the revised regulation eliminated that objection. In effect, it restated the "one-pill rule" as it applied to the substances. The Medical and Pharmacy Boards, however, continued to object to the regulation. While conceding that the revised version limited prescriptions by homeopathic physicians of certain schedule II controlled substances (opiates and other narcotics), the Boards contended that it conferred *carte blanche* authority on homeopathic physicians to prescribe, in allopathic doses, all other allopathic drugs, all controlled substances except the narcotics and opiates listed in schedule II, and all dangerous drugs. In particular, they objected that the revised regulation authorized homeopathic physicians to prescribe allopathic doses, certain enumerated chelating agents and to administer them by means of "intravenous infusion."

Operating on the assumption that these substances would be prescribed in the course of administering chelation therapy, a practice expressly authorized by the regulation's definition of orthomolecular therapy, the revised R213-07 permitted, by regulation, two practices---chelation and intravenous infusion---that had been expressly denied to homeopathic physicians by the Assembly amendments to A.B. 286.

Following this evidence and after full discussion, the Legislative Commission by a close vote failed to object to the revised regulation and it therefore became effective. Under NRS 233B.067 and 233B.0675, unless a majority of the Commission objects to a regulation, the Director of the Legislative Counsel Bureau is obliged to file the regulation with the Secretary of State and it becomes effective as of the date of filing. This was, accordingly, done and the regulation became effective on December 18, 1998. (*See* letter from Lorne J. Malkiewich to Dean Heller, December 18, 1998.)

### D. The Attorney General Declares the Regulation Invalid

The 1999 session of the Legislature convened on February 2. Although numerous members of the Legislative Commission had indicated that the scope of the practice of homeopathy would be addressed at the session, in fact, no such legislation was passed or even requested. The Pharmacy Board, however, solicited the opinion of the Attorney General on the question of whether a singly-licensed homeopathic physician administering the alternative or non-traditional therapies described in the adopted regulation could prescribe controlled substances or dangerous drugs. The Attorney General responded on February 11, 1999. (*See* Nev. Op. Att'y Gen. 99-06 (A.G.O. 99-06).)

After a brief recapitulation of the amendment and passage of A.B. 286 of the 1997 Legislature and evolution of R213-97, the Attorney General concluded that the regulation was invalid. The Attorney General reached this conclusion because, during a Legislative Commission hearing, members of the Homeopathic Board had, in her

opinion, expressed "an intent to interpret the phrase 'pharmaceutical preparations' as permitting a singly licensed homeopathic physician to prescribe some controlled substances and dangerous drugs . . . We believe this interpretation renders the regulation invalid . . ." The Attorney General also concluded that:

> When the Legislature specifically deleted the term 'pharmaceutical medicine' from the definition of homeopathy, its clear intent in enacting the remainder of A.B. 286 was to prohibit singly licensed homeopathic physicians from having the ability to prescribe controlled substances and dangerous drugs in the same manner as an allopathic physician ... We believe that our conclusion in Op. Nev. Att'y Gen. No. 93-21 (September 20, 1993), continues to accurately describe the limited ability of singly
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> licensed homeopathic physicians to posses, dispense, and administer controlled substances and dangerous drugs.

Unlike the 1985 "informal" opinion, this opinion was issued publicly and was made public during the course of the Legislative session. Nevertheless, the Legislature took no further action and no further inquiries were made until you requested this opinion following the conclusion of the session.

## II. Analysis

With the preceding background in place, we will now analyze each of your questions separately. Your first question is whether the Attorney General's opinion is correct. It is the opinion of this office that it is not.

### A. The Attorney General's Opinion No. 99-06

As a preliminary matter, we note that the "opinions of the attorney general do not constitute binding legal authority or precedent." *Goldman v. Bryan*, 106 Nev. 30, 42 (1990). "The opinion of the state attorney general is advisory and not a binding interpretation of state law." *Nevada Highway Patrol Ass'n v. State*, F.2d 1549, 1554, n.6 (1990). See also *Tahoe Regional Planning Agency v. McKay*, 769 F.2d 534, 539 (9th Cir. 1985); *Weston v. County of Lincoln*, 98 Nev. 183 (1982); and *Cannon v. Taylor*, 88 Nev. 89 (1972). Consequently, even if A.G.O. 99-06 were correct, it would not be binding. In any event, however, the Attorney General possesses neither the statutory nor the constitutional power to invalidate regulations. Therefore, it is the opinion of this office the A.G.O. 99-06 is necessarily incorrect to the extent that it purports to claim that the Attorney General has the authority to invalidate a regulation after the regulation has been adopted in compliance with all the procedures required under chapter 233B of NRS and has been filed with the Secretary of State.

Section 2 of Article 3 of the Nevada Commission expressly provides for legislative review and nullification of administrative regulations. It states that:

> If the legislature authorizes the adoption of regulations by an executive agency which bind persons outside the agency, the legislature may provide by law for:
>
> (a) The review of these regulations by a legislative agency before their effective date to determine initially whether each is within the statutory authority for its adoption;
>
> (b) The suspension by a legislative agency of any such regulation which appears to exceed that authority, until it is reviewed by a legislative body composed of members of the Senate and Assembly which is authorized to act on behalf of both houses of the legislature; and
>
> (c) The nullification of any such regulation by a majority vote of that legislative body, whether or not the regulation was suspended.

Acting pursuant to this constitutional grant of authority, the Legislature has amended chapter 233B of NRS, the Nevada Administrative Procedure Act. In chapter 233B of NRS, the Legislature provided, inter alia, the exclusive avenues for determining the pre-enforcement validity of a regulation.[7] Under NRS 233B.110, "[t]he validity or applicability of any regulation may be determined in a proceeding for a declaratory judgment in the district court" by any plaintiff who alleges that "the regulation, or its proposed application, interferes with or impairs, or threatens to interfere with or impair [his] legal rights or privileges . . " Alternatively, "[a]n agency may institute an action for declaratory judgment to establish the validity of any one or more of its own regulations." In this proceeding, "[t]he court shall declare the regulation invalid if it finds that it violates constitutional or statutory provisions or exceeds the statutory authority of the agency." A.G.O. 99-06 concluded that a regulation is invalid if it "exceeds the statutory authority delegated by the Legislature to an administrative agency." This is clearly correct, but as NRS 233B.110 makes clear, when the regulation exceeds its authority, it is the court, not the Attorney General, that is required to "declare the regulation invalid."[8] Chapter 233B of NRS expressly provides a role for the Attorney General in all actions to determine the validity of a regulation. The plaintiff in any such action is required to serve a copy of the complaint upon the Attorney General, who is "entitled to be heard." (Subsection 3 of NRS 233B.110.)[9]

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[7] Any person who is actually harmed by the enforcement of a regulation or by a state officer acting pursuant to the regulation may bring an action for damages against the state or the officer, during the course of which the validity of the regulation may be brought into issue and resolved by the court. The Legislature's intent in enacting NRS 233B.110 was to permit the validity of regulations to be determined even before they are enforced.

[8] It could be argued that the Attorney General is not asserting a power to declare a regulation invalid, but is merely expressing that which is evident—a regulation that exceeds its authorizing statute is void. Without disputing the accuracy of this conclusion, it is the opinion of this office that because chapter 233B of NRS provides detailed procedures for establishing the validity of regulations, it cannot reasonably be suggested that the Legislature intended chapter 233B of NRS to be self-executing.

[9] Although chapter 233B of NRS gives the sole means for declaring a regulation invalid, NRS 233B.100 provides that "[a]ny regulation of any agency is subject to amendment or suspension by the governor

The statutory scheme embodied in chapter 233B of NRS assigns distinct functions to the judicial branch of government and to the Attorney General. It limits the Attorney General's role to "being heard" by the court. This assignment and limitation points up another objection to the Attorney General's assertion of the authority to declare

administrative regulations invalid, which is the constitutional objection inherent in the doctrine of the separation of powers. Section 1 of Article 3 of the Nevada Constitution states that:

> The powers of the Government of the State of Nevada Shall be divided into three separate departments,---the Legislative,---the Executive and the Judicial; and no persons charged with the exercise of powers properly belonging to one of these departments shall exercise any functions, appertaining to either of the others, except in the cases expressly directed or permitted in this constitution.

The remainder of Article 3 confers on the Legislature the authority to nullify administrative regulations before they become effective. Similarly, the power to interpret statutes and regulations and to declare them invalid is entrusted to the courts in implicit reliance on the constitutional principle that "[i]t is emphatically the province and duty of the judicial department to say what the law is." *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177 (1803) (Marshall, C.J.). For the Attorney General to assert a power to invalidate regulations clearly violates the doctrine of the separation of powers by exercising functions appertaining to both of the other branches of government.

The Attorney General is obviously aware of her constitutional role and it is unlikely that she intended to exceed it. Rather, it is probable that her declaration of the invalidity of R213-97 contained in A.G.O. 99-06 merely represents her prediction of what a court of competent jurisdiction would be likely to declare if the question were posed to the court. Alternatively, the opinion could be meant to communicate the legal argument against the regulation's validity that the Attorney General would make in an action at law brought to determine that question. However, even regarded in this light, A.G.O. 99-06 is flawed in several particulars that make it unlikely to be a fully reliable guide to future judicial conduct on this issue.[10]

First, A.G.O. 99-06 states that a "regulation cannot restore a power that the

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pursuant to the provisions of NRS 416.060." This latter section, however, becomes effective only "[u]pon the proclamation of a water or energy emergency," and limits the amendment or suspension power to the extent necessary to lessen the adverse impact of that emergency.

[10] To the extent that A.G.O. 99-06 is intended as a prediction of judicial behavior, rather than an advocate's brief, it commits additional errors of omission in that it fails to consider fundamental principles and rules of statutory construction that a court would be bound to apply. We discuss these principles and rules in response to your third question.

Legislature specifically took out of a piece of legislation." This principle is sound, but it does not apply to this case in the manner suggested by the Attorney General. The power specifically taken out of A.B. 286 by the Legislature---expansion of the definition of homeopathy to include the unlimited practice of "pharmaceutical medicine," i.e., complete authority to prescribe allopathic drugs in allopathic doses---is not the same as the authority granted by the regulation. This latter authority consists only of a limited power to prescribe or use certain "pharmaceutical preparations" in certain alternative

therapies. Because these two grants of power are not identical, the regulation does not "restore" a power specifically removed from the legislation.[11]

Moreover, A.G.O. 99-06 is internally inconsistent. The opinion declares that the regulation is invalid because it could be interpreted "as permitting a singly licensed homeopathic physician to prescribe some controlled substances and dangerous drugs." Nevertheless, A.G.O. 99-06 concludes by reaffirming A.G.O. 93-21 which declared that "[I]t is clear . . . that a homeopathic physician practicing homeopathically could legally obtain, possess, and administer some dangerous drugs and controlled substances for the manufacture of homeopathic remedies. Additionally, a homeopathic physician may also prescribe those dangerous drugs and controlled substances allowed by NRS 630A.040." Besides this obvious contradiction, A.G.O. 99-06 commits the non sequitur of concluding that an interpretation of the regulation that would permit singly-licensed homeopathic physicians to prescribe "some" controlled substances and dangerous drugs renders the regulation invalid because the Legislature clearly intended to prohibit singly-licensed homeopathic physicians from having the unlimited ability to prescribe any and all controlled substances and dangerous drugs "in the same manner as an allopathic physician."

In addition, A.G.O. 99-06 is, simultaneously, underinclusive as well as overbroad. It limits its consideration to the effect of the legislative deletion of the power to practice "pharmaceutical medicine" from A.B. 286. However, as previously noted, the Assembly Committee on Commerce also eliminated "chelation therapy" and "intravenous infusion" from A.B. 286. Moreover, A.B. 286 expanded the regulatory power of the Homeopathic Board over its licensees, but specifically rejected language that would have given that board the power to grant licenses to prescribe allopathic drugs. Finally, the bill expanded the scope of the practice of homeopathy to encompass seven alternative therapies, some of which require the administration of medicinal substances of one kind or another. The authority of licensed homeopathic physicians to write prescriptions under A.B. 286 and R213-97 cannot be adequately evaluated if all the powers granted and refused are not taken into consideration. On the other hand, A.G.O. 99-06 declares R213-97 invalid in its entirety, eliminating the authority of homeopathic physicians to practice noninvasive

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[11] This regulation does, however, present a field for the application of the Attorney General's principle. The alternative practices of "chelation therapy" and "intravenous infusion" were deliberately amended out of the statute by the Assembly Committee on Commerce, but are restored by regulation as constituent parts of the practice of orthomolecular therapy. We will discuss this aspect of the regulation's validity subsequently.

electrodiagnosis, cell therapy, herbal therapy, neuromuscular integration and nutrition, when these practices are expressly authorized by A.B. 286, and no opposition of any kind has been raised with respect to these therapies.

Finally, the Attorney General's invalidation of the regulation is premature A.G.O. 99-06 is not premised on a claim that the language of the regulation necessarily conflicts with its authorizing statute. Instead, A.G.O. 99-06 concludes that a particular "interpretation makes the regulation invalid." However, the Homeopathic Board has not in fact, issued any such interpretation. A.G.O. 99-06 rests on the Attorney General's perception that "Board members [of the Homeopathic Board] clarified in the Legislative Commission an intention to interpret the phrase 'pharmaceutical preparations' as permitting a singly licensed homeopathic physician to prescribe some controlled substances and dangerous drugs . . ." Even if that were a valid basis for invalidating the regulation, which, as previously discussed, it is not, there were never more than two of the Homeopathic Board's five members present at either meeting of the Legislative Commission. * Assuming that the Attorney General correctly perceived the intended interpretation of those two members, only one of them spoke, they do not constitute a majority of the Board. Consequently, this seems a slender basis on which to invalidate even the portion of the regulation that could be subject to that hypothetical interpretation. When employed to invalidate all the other aspects of the regulation, even this tenuous basis of rationality is lost. Therefore, the Attorney General cannot declare the regulation invalid on the basis of a belief that the Homeopathic Board might at some future time choose to interpret its regulation in an offensive manner.

A.G.O. 99-06, does, however, achieve one valuable insight. It concludes that in enacting A.B. 286, the Legislature evidenced the clear intent that homeopathic physicians were not to enjoy the same unlimited authority to prescribe allopathic drugs in allopathic doses that is possessed by allopathic or osteopathic physicians. This insight, however, requires further evaluation. A.G.O. 99-06 states that "[w]hen the Legislature specifically deleted the term 'pharmaceutical medicine' from the definition of homeopathy, its clear intent in enacting the remainder of A.B. 286 was to prohibit the singly licensed homeopathic physician from having the ability to prescribe controlled substances and dangerous drugs in the same manner as an allopathic physician." As previously pointed out, the correct from of reference for determining legislative intent should be the act taken as a whole, including parts adopted, as well as all of the powers eliminated, during the amendment process. It is the opinion of this office that a more accurate way of characterizing the legislative intent behind A.B. 286 is that the Legislature, even while significantly expanding the authority of homeopathic physicians to practice alternative medicine and while enlarging the autonomy of the profession to regulate itself, ultimately refused to alter the status quo that declares that a license to practice homeopathic medicine does not confer the authority to prescribe allopathic drugs in allopathic doses in the same manner as an allopathic physician. We will return to this discussion of the correct determination of legislative intent in our response to your third question. Before

* The Board actually consisted of seven members.

doing so, however, we turn to your second question. Is the regulation effective, is it valid, and if so, what authority at present do homeopathic physicians have to prescribe allopathic medications, including controlled substances and dangerous drugs?

### B. Effectiveness, validity and resulting authority of R213-97

#### 1. Effectiveness

It is the opinion of this office that the regulation R213-97 is currently effective. The statutory scheme of chapter 233B of NRS is unambiguous in this regard. A permanent regulation becomes effective as of the date the Legislative Counsel files it with the Secretary of State, unless a later date is specified in the regulation. (NRS 233B.070.) The Legislative Counsel has a non-discretionary duty to file such regulations once certain procedural requirements were fulfilled.[12] In this instance, all the statutory procedural requirements were satisfied. The Legislative Commission failed to object to the regulation before it was filed with the Secretary of State and it may not do so now. By the same token, the 1999 Legislature could only have nullified the regulation if the Legislative Commission had voted to suspend the filing of the regulation. (NRS 233B.0675.) The Legislative Commission's failure to object deprived the full Legislature of its opportunity to nullify the regulation directly. In the absence of a constitutional amendment or new legislation, the regulation is beyond the reach of the legislative branch.[13] Accordingly, it is the opinion of this office that, pursuant to NRS 233B.0675, the regulation became effective on December 18, 1998, and until a court of competent jurisdiction enjoins its enforcement or declares it invalid or the Homeopathic Board adopts an amendment, it remains in effect and has the force of law. (*See* NRS 233B.040.) This brings us to the second part of your question, is the regulation valid?

#### 2. Validity

Like a statute, an effective regulation must be presumed to be valid until a court of competent jurisdiction determines that it is not. (1A *Sutherland Statutory Construction*, §31.02 (5th ed. 1993 & Supp. 1999); see also *Immigration and Naturalization Service v. Chada*, 103 S. Ct. 2764, 2784 (1983).) Therefore, presuming, as we must, that R213-97 is valid, this brings us to the third part of your question. Under the statutes and regulations currently in effect, what authority does a homeopathic physician have to possess, administer, dispense or prescribe allopathic drugs, controlled substances and dangerous drugs?

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[12] Before July 1, 1999, the Legislative Counsel's responsibilities concerning the regulatory process were vested in the Director of the Legislative Counsel Bureau. (See sections 43 to 49, inclusive, of chapter 463, Statutes of Nevada 1999, at pages 2203-07.)

[13] In any event, NRS 233B.0675 required the Legislature to nullify the regulation before the 30th day of the Legislative session. Even if the extension of this deadline to the final day of the session that was enacted in 1999 (section 1 of chapter 182, Statutes of Nevada 1999, at page 903, effective May 20, 1999) could be made to apply to apply to R213-97, that date has also long since passed.

### 3. The authority to write prescriptions

As a preliminary matter, we note that a dually-licensed homeopathic physician has the authority to write prescriptions, including prescriptions for allopathic drugs in allopathic doses, that he enjoys under his allopathic (or osteopathic) license. However, it remains the opinion of this office, as we advised you in 1998, that the powers and accountability of dually-licensed homeopathic physicians can only be determined with reference to the capacity in which they are practicing at any given time. (See letter from Brenda J. Erdoes and Eileen O'Grady to Senator Ann O'Connell, March 19, 1998.) A licensed homeopathic physician, when practicing homeopathically, is not accountable to the Medical Board because he is not exercising any of the rights or privileges conferred by virtue of an allopathic license issued by that Board. This conclusion, although in conflict with Attorney General's Opinion No. 98-01, is in complete accord with her earlier A.G.O. 93-21.[14] So, we do not believe that there is any difference between the authority of singly- and dually-licensed homeopathic physicians to write prescriptions when they are practicing homeopathically. The definitions of R213-97 concern only the nontraditional, alternative therapies recently incorporated into homeopathic medicine by virtue of A.B. 286. Nothing in that regulation changes, or purports to change, any aspect of traditional practice. Consequently, it is the opinion of this office that a homeopathic physician, practicing traditionally, does so with the same authority and under the same

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[14] It may be helpful to remind you of the circumstances surrounding the Attorney General's Opinion No. 98-01. In August, 1997, the Medical Board asserted that A.B. 286 had granted it exclusive disciplinary power over all licensed homeopaths who were also licensed by the Medical Board. This drew a formal protest from Senator Townsend as a misinterpretation of A.B. 286. (See letter from Senator Randolph J. Townsend to Attorney General Frankie Sue Del Papa, November 4, 1997.) Shortly thereafter, the Homeopathic Board requested an opinion from the Attorney General as to the proper relationship between the two boards, which was issued on January 13, 1998. (See Nev. Op. Att'y Gen. 98-01 A.G.O. 98-01).) The primary focus of that opinion concerned the obligations of a dually-licensed physician when one board forbade a medical procedure that was condoned by the other. The Attorney General concluded that the Legislature had intended the Medical Board's disciplinary jurisdiction to be exclusive. Thereafter, Senator O'Connell, you requested the opinion of this office as to the soundness of A.G.O. 98-01. We concluded that the Attorney General had overstated the powers of the Medical Board and suggested, instead, that "the Medical Board may not regulate the practices of a person who is licensed to practice both allopathic and homeopathic medicine while that person is actually practicing homeopathy within the scope of chapter 630A of NRS." (Letter from Brenda J. Erdoes and Eileen O'Grady to Senator Ann O'Connell, March 19, 1998.) More generally, we suggested that the clear intent of the legislative scheme had been to require that questions regarding dually-licensed physicians could only be answered after establishing in which capacity —allopathic or homeopathic—the physician was practicing. Note that this conclusion is consistent with the Attorney General's earlier opinion that each license confers its own separate set of powers and limitations, and that at any given moment a dually-licensed physician is practicing one form of medicine or the other, and not some hybrid or intermediate form. (See A.G.O. 93-21.) Thus, both the Attorney General and the Legislative Counsel have endorsed the proposition that a dually-licensed homeopathic physician cannot use his allopathic license to prescribe allopathic drugs in allopathic doses if his intention is to effect a homeopathic treatment. The factual context for A.G.O. 93-21 concerned the practice of chelation therapy, a form of medicine that we will examine in more detail in response to your third question.

limitations that he has since 1987. The limits of this practice are fully and competently set out in the Attorney General's Opinion No. 93-21. Having said this, it must be remembered that A.B. 286 bifurcated the practice of homeopathy into what we have called "traditional" or "classical" homeopathy and "complex homeopathy" or, more accurately, certain "alternative therapies." These practices consist of "[n]oninvasive electrodiagnosis, cell therapy, neural therapy, herbal therapy, neuromuscular integration, orthomolecular therapy and nutrition" as these practices have been defined in R213-97. As with the earlier distinction between allopathic and homeopathic licenses, we believe that it is possible to determine the authority of a homeopathic physician to write prescriptions only after determining which homeopathic therapies---"tradition" or "alternative"---he is engaged in.

**(a) Traditional**

Little additional needs to be said about the authority of a homeopathic physician to write prescriptions when practicing traditional or classical homeopathy. The limits of this power are contained in NRS 0.040 and chapters 453, 454, and 639 of NRS, as well as in NRS 630A.040. As we previously indicated, it is the opinion of this office that A.G.O. 93-21 accurately interpreted the statute, the operative portion of which has not been amended in a way that significantly alters this conclusion. Thus, homeopathic physicians may prescribe, dispense and administer traditional homeopathic remedies as medically appropriate according to the standards applicable to the homeopathic tradition. With respect to allopathic medications, including controlled substances or dangerous drugs, homeopathic physicians may write prescriptions for a single pill of such substances, but only for the purpose of diluting it and compounding it into a homeopathic preparation, only if the allopathic drug is found in the Homeopathic Pharmacopoeia and only if the resulting diluted dosage is in accordance with dosages found in that pharmacopoeia.

**(b) Alternative therapies**

Homeopathic physicians, when practicing one of the alternative therapies authorized by A.B. 286 and defined in R213-97, have some additional authority to write prescriptions for allopathic drugs. It should be re-emphasized, however, that we believe this power to be practice-specific. For example, in the hearing on A.B. 286, the representatives of the homeopathic physicians expressed a desire to be able to prescribe antibiotics to patients suffering from strept throat. A homeopathic physician who desires to prescribe antibiotics, that is, allopathic drugs in allopathic doses according to allopathic principles, is not practicing classical homeopathy. Neither, as far as we can tell from the definitions contained in R213-97, is he practicing one of the alternative therapies. Consequently, nothing in the statute or regulation confers any increased authority to prescribe antibiotics. A homeopathic physician with an allopathic or osteopathic license may prescribe antibiotics under these circumstances, but when he does so, he is practicing under his medical license, his authority to write prescriptions is

determined by that license, and he is accountable to the Medical, not the Homeopathic Board for any complaints arising from that treatment. A singly-licensed homeopathic physician did not have the authority to prescribe antibiotics in these circumstances before the passage of A.B. 286 and the adoption of R213-97. Such a physician has not gained any power to do so under either measure. Therefore, a homeopathic physician, by virtue of his homeopathic license, does not have a general or unlimited power to practice allopathic medicine, including the prescription of allopathic drugs in allopathic doses. However, when practicing a legislatively sanctioned alternative therapy, it is the opinion of this office that a homeopathic physician, so long as he complies with all state and federal laws and regulations applicable to prescription drugs, may prescribe in allopathic doses:

1. Any Controlled substance listed in schedule I, II, III, IV or V as set forth in chapter 453 or NRS, so long as both administration and dosage are medically appropriate according to the standards applicable to that alternative therapy, except that a homeopathic physician may not prescribe "narcotic drugs and opiates that are listed as schedule II controlled substances pursuant to chapter 453 of NRS, except as those substances may be described for use in the official Homeopathic Pharmacopoeia of the United States." (R213-97.)

2. Any dangerous drug that is defined in chapter 454 of NRS so long as both administration and dosage are medically appropriate according to the standards applicable to that alternative therapy.

3. Any other allopathic drug available by prescription so long as both administration and dosage are medically appropriate according to the standards applicable to that alternative therapy.

Finally, this brings us to your third question, is the authority to write prescriptions granted by R213-97 in conformity with the intent of the Legislature in enacting A.B. 286?

### C. Legislative intent

We believe that the best way of addressing the question of whether R213-97 conforms to legislative intent is to examine how a court would be likely to rule if this regulation were challenged in a legal action, whether brought as an action for a declaratory judgment, a suit for a writ of mandamus or an action for damages. According to NRS 233B.110, a court in such a position "shall declare the regulation invalid if it finds that [the regulation] violates constitutional or statutory provisions or exceeds the statutory authority of the agency."

Courts determining whether a particular regulation is beyond the power granted to an administrative agency, "must not only interpret the statute to determine the powers conferred but also the regulation to determine whether its provisions comply with the statute." 1A *Sutherland Statutory Construction*, §31.06. In doing so, judges apply standard principles and rules of statutory construction, as well as special rules applicable

to regulations only. 1A *Sutherland Statutory Construction*, §31.06. These rules, however, are not absolutes and do not permit us to predict with certainty what outcome any particular judge might reach. Consequently, we will present first the considerations that militate in favor of the regulation's validity. We will then present the countervailing considerations and, finally, our opinion as to which outcome is the more likely.

**1. Arguments in favor of validity**

The first applicable principle on rule of statutory construction accords to regulations the same presumption in favor of their validity that applies to statutes. 1A *Sutherland Statutory Construction*, §31.02. A corollary of this presumption is that the party challenging the validity of the regulation bears the burden of proving its invalidity.[15] Any interpretation of the regulation must take place against the backdrop of these presumptions favoring the validity of the regulation.

In addition, the rules of statutory construction provide that "[w]hen presented with a question of statutory interpretation, the intent of the legislature is the controlling factor and, if the statute under consideration is clear on its face, a court cannot go beyond the statute in determining legislative intent. If, however, the statute is ambiguous, it can be construed "in line with what reason and public policy would indicate the legislature intended . . ." *Robert E. v. Justice Court of Reno Township*, 99 Nev. 443, 445, 664 P.2d 957, 959 (1983) (internal citation omitted). Moreover, the court may also examine the legislative history of a provision if doing so would be "useful" in determining legislative intent. *Del Papa v. Board of Regents of the University and Community College System of Nevada*, 114 Nev. Adv. Op. 50, at p. 5, 956 P.2d 770 (1998). "A statute or portion thereof is ambiguous when it is capable of being understood by reasonably well-informed persons in either of two or more senses." *Robert E. v. Justice Court*, 99 Nev. at 445, 664 P.2d at 959 (internal citation omitted); see also *McKay v. Board of Supervisors*, 102 Nev. 644, 649, 730 P.2d 438, 442 (1987).

It can be argued that A.B. 286 is ambiguous as many of the terms used in the bill are capable of being understood in two or more senses. For example, as previously mentioned, none of the alternative therapies added to the definition of homeopathy would be considered "homeopathic" as that term has been traditionally used. Thus, the chief witness in favor of expanding the definition of homeopathy to include these alternative therapies testified that "when [A.B. 286 talks about neural therapy, you are not talking about homeopathy. When it talks about orthomolecular therapy and herbalist medications, you're not talking about homeopathy." He also stated that there was "no such thing" as homeopathic neuromuscular integration. (Testimony of F. Fuller Royal, Minutes, Legislative Commission, December 18, and June 26, 1998.) Besides this inherent ambiguity, a particular ambiguity attaches to the most controversial of the

[15] As suggested previously, if A.G.O. 99-06 were considered in the nature of a brief submitted to a court by the Attorney General as provided in NRS 233B.110, we believe that the opinion would be insufficient to overcome this presumption of validity.

contested terms, "orthomolecular therapy." This term has a definition in conventional medical dictionaries that does not correspond in every particular with the manner in which that therapy is conducted by the alternative medical community. (*See* Testimony of Robert Barengo, Minutes, Legislative Commission, June 28, 1998.) However, Dr. Royal testified, and it was conceded, that the definitions of these alternative therapies adopted in the regulations employed correctly the meaning of these practices bear in the sources regarded as authoritative by the alternative medicine community. (See Testimony of F. Fuller Royal, Minutes, Legislative Commission, June 28 and December 18, 1998; Testimony of Robert Barengo, Minutes, Legislative Commission, June 28, 1998.) In light of these ambiguities, a court would not be able to rely solely on the language of the statute to determine the Legislative intent behind A.B. 286 as a predicate to determining whether R213-97 conforms with that intent. Instead, the court would be fully justified in examining all the extrinsic sources available, including the legislative history of A.B. 286, to attempt to discern the intent of the Legislature.

Moreover, when doubt arises as to the proper interpretation of a statute affecting an administrative agency, the Nevada Supreme Court has found that the interpretation of the agency that is charged with the administration and enforcement of the statute is persuasive evidence of its meaning. *Nev. Power Co. v. Public Serv. Comm'n*, 102 Nev. 1, 4 (1986); see also *Dep't of Human Resources v. UHS of the Colony Inc.*, 103 Nev. 208, 211 (1987) (stating that an administrative construction that is within the language of the statute will not readily be disturbed by the courts); *Roberts v. State*, 104 Nev. 33, 39, 752 P.2d 221, 225, (1988). The theory behind this interpretation is that the Legislature is charged with having knowledge of the manner in which the statutes it enacts are carried out. Where the legislature "has had ample time to amend an administrative agency's reasonable interpretation of a statute, but fails to do so, such acquiescence indicates the interpretation is consistent with legislative intent." *Hughes Properties v. State of Nevada*, 100 Nev. 295, 298, 680 P.2d 970, 972 (1984) (citation omitted). "[N]early contemporaneous constructions of state statutes by administrative agencies charged with their implementation are entitled to great weight, especially when, as in the present case, the legislature fails to repudiate the agency's construction." *Roberts v. State*, 104 Nev. at 39, 752 P.2d at 225 (citations omitted). This citation is particularly applicable inasmuch as the final decision of the Legislative Commission failing to object to the regulation took place less than 6 weeks before the opening of the next session of the legislature. Numerous members of the Legislative Commission had suggested during their discussions that the matter be referred to the Legislature. However, the fact that the Legislature not only did not pass, but did not even request, a bill to modify the scope of

the practice of homeopathy may well justify a conclusion that the Legislature did not believe that the regulation violated its intent in amending chapter 630A of NRS. And "[a]lthough not controlling, the legislature's construction of its own act is persuasive in ascertaining the act's meaning." *Roberts*, 104 Nev. at 40, 752 P.2d at 225.

Standard rules of statutory construction direct that statutes should be read and interpreted as a whole. 2A *Sutherland Statutory Construction* § 46.05; *K.J.B., Inc. v. Second Judicial Dist. Court*, 103 Nev. 473, 476 (1987). "'Courts must construe statutes

. . . to give meaning to all of their parts and language . . . The court should read each sentence, phrase, and word to render it meaningful within the context of the purpose of the legislation.'" *Del Papa v. Reagents*, 114 Nev. Adv. Op. 50, at p. 3, quoting *Board of County Comm'rs v. CMC of Nevada*, 99 Nev. 739, 744, 670 P.2d 102, 105 (1983) (citations omitted). Taken as a whole, it seems clear that the intent of the Legislature was to expand the scope of homeopathic practice, but not to increase it so far that it became an independent license to engage in the unlimited practice of allopathic medicine. It is evident that the alternative therapies defined by R213-97 are limited in scope and do not constitute the unlimited practice of allopathic medicine. Consequently, it can be argued that the regulation is consistent with legislative intent and is, therefore, valid.

2. Arguments against validity

The strongest arguments against the validity of R213-97 originate in the legislative history of A.B. 286. Standard rules of statutory construction permit the use of legislative history to establish legislative intent when a statute is ambiguous. The legislative history of A.B. 286 reveals that the Assembly Committee on Commerce deliberately removed the terms "intravenous infusion, chelation therapy, and pharmaceutical medicines" from the bill. This is consistent with the notion that it was the intent of the Legislature that homeopathic physicians were not to be authorized to engage in these practices. It is well settled that "[a]dminstrative regulations cannot contradict or conflict with the statute they are intended to implement." *Roberts v. State*, 104 Nev. at 37, 752 P.2d at 223. As the Attorney General argued, a regulation "cannot restore a power that the Legislature specifically took out of a piece of legislation." (A.G.O. 99-06.) Thus, to the extent that R213-97 authorizes homeopathic physicians to practice intravenous infusion and chelation, and to prescribe some pharmaceutical preparations, it can be argued that it violates legislative intent and is, necessarily, invalid.

It must be noted, however, that some problems occur with this argument. First, the Nevada Supreme Court has expressly proscribed the use of legislators' statements of opinion as a means of determining legislative intent. "'[I]n construing a statute we do not consider the motives or understands of individuals who cast their votes in favor of it. . . . [Even if] the legislator whose motives are proffered actually authored the bill in controversy; no guarantee can issue that those who supported this proposal shared his view of its compass.'" *A-NLV Cab Co. v. State Taxicab Authority*, 108 Nev. 92, 95 (1992), quoting *Cal. Teachers Ass'n v. San Diego Com. College*, 621 P.2d 856, 860 (Cal. 1981) (citations and internal quotations omitted). "A legislator's statement is entitled to consideration, however, when it is a reiteration of legislative discussion and events leading to adoption of proposed amendments, rather than merely an expression of personal opinion." See also *Khoury v. Maryland Casualty Co.*, 108 Nev. 1037, 1040 (1992). In this instance, however, even assuming that the Legislators' recollections were entitled to consideration, they appear to be offsetting. Members of the Assembly recall that the three therapies were removed by amendment for the deliberate purpose of excluding them from the scope of homeopathic practice. Members of the Senate recall that the intent behind their removal was merely to eliminate redundancy and that the

eliminated terms were available therapies already included within the other approved therapies.

A second difficulty was referred to earlier. It is not readily apparent that the authority to engage in the unlimited practice of allopathic medicine that may have been removed by elimination of the term "pharmaceutical medicine" from the statute is the same as the limited authority to prescribe some chemical substances that is granted by virtue of the regulation's use of the term "pharmaceutical preparation." This is especially so because the authority to prescribe these latter substances is constrained by the requirement of medical appropriateness in the context of a specific authorized alternative therapy. In any event, it is undeniable that the two other statutory terms eliminated by the Assembly Committee on Commerce---"intravenous infusion" and "chelation therapy"---are the same as the two terms restored by the regulation. The two terms are related. Chelation therapy is recognized in conventional medical circles as a technique for treating victims of heavy metal poisoning. The most common example, apparently, involves miners whose blood and bones show unusually high concentrations of lead. Certain drugs (chelating agents) with the chemical property of binding to heavy metals at the molecular level are introduced, commonly by means of intravenous infusion, into the body of the miner. The heavy metals abandon their chemical bonds with the body's tissues and fluids in favor of combining with the chelating agents. When these chelating agents are subsequently eliminated from the body, the heavy metals are eliminated as well. Practitioners of alternative medicine contend that chelation can be used to remove other harmful substances from the bodies of patients. Apparently, the most common example of this alternative practice is the treatment of arteriosclerosis by chelating the harmful plaque build-up in arterial walls. The efficiency of this treatment for its alternative purpose has not been demonstrated to the satisfaction of the allopathic medical community. Nevertheless, in 1998, the Medical Board refused to adopt a regulation that would have prohibited any allopathically licensed physician, including any dually-licensed homeopathic physician, from using chelation therapy except to remove heavy metals from a patient's body. (*See* "Nevada doctors battling," *Las Vegas Review Journal*, December 3, 1997; "Continued use of alternative medicine to treat hear bypass surgery OK'd," *Las Vegas Review Journal*, January 30, 1998.) In any event, chelation therapy, even when practiced alternatively, requires the use of allopathic dosages of allopathic substances. Moreover, any allopathic physician, including a dually-licensed homeopathic physician, may perform chelation in its conventional or alternative mode. For this reason, it would not be unreasonable for a court to find R213-97 invalid to the extent that it authorized a singly-licensed homeopathic physician to perform chelation, especially by means of intravenous infusion.

### 3. On balance

It is the opinion of this office that when A.B. 286 and its legislative history are examined as a whole, the legislative intent behind the bill was to extend the scope of the licensed practice of homeopathic medicine and to increase the power of the Homeopathic Board to regulate that practice, but that it was not the intent to authorize singly-licensed

homeopathic physicians the unlimited right to practice allopathic medicine in the same manner as allopathic physicians. More particularly, the Legislature intended homeopathic physicians to enjoy expanded authority to write prescriptions with regard to certain allopathic medicines, but only to the extent required in practicing certain enumerated alternative therapies. In general, the definitions contained in the regulation of the Homeopathic Board, R213-97, do not exceed the Board's statutory authority and are consistent with legislative intent. We think it highly likely that a court of competent jurisdiction, if asked, would agree. We believe, however, that with respect to the definition of one alternative therapy, orthomolecular medicine, particularly that branch of it that concerns chelation or other forms of detoxification by means of intravenous infusion, there is a significant question whether that portion of the regulation is consistent with legislative intent. Nevertheless, assuming that a court would grant the regulation its presumption of validity, would take into consideration: (1) that the Legislative Commission did not object to the regulation on the grounds that it violated legislative intent; and (2) that the Legislature as a whole, with knowledge of the existence of the controversy over this provision, took no corrective action during the 1999 session, we are inclined to believe that the court would be more likely than not to uphold the validity of this element of the regulation as well. In any event, we conclude that such a court would not invalidate the regulation in its entirety.

## III. Conclusions

It is the opinion of this office that the declaration of the invalidity of R213-97 contained in Attorney General Opinion No. 99-06 is legally null. Only a court of competent jurisdiction may invalidate a regulation and until such a court does so, R213-97, having satisfied all the procedural requirements of the Nevada Administrative Procedure Act, remains in effect and must be presumed to be a valid regulation.

It is the further opinion of this office that licensed homeopathic physicians may practice all of the therapies defined in R213-97, including chelation therapy and other forms of detoxification by means of intravenous infusion. A reasonable interpretation of the statutes and regulations, currently in effect, including R213-97, establishes that homeopathic physicians possess the following authority to write prescriptions by virtue of their homeopathic licenses:

1. When practicing traditional or classical homeopathy, they may prescribe, dispense and administer traditional homeopathic remedies as medically appropriate according to the standards applicable to the homeopathic tradition. With respect to allopathic medications, including controlled substances or dangerous drugs, homeopathic physicians may write prescriptions for a single pill of such substances, but only for the purpose of diluting it and compounding it into a homeopathic preparation, only if the allopathic drug is found in the Homeopathic Pharmacopoeia and only if the resulting diluted dosage is in accordance with dosages found in that pharmacopoeia.

2. When practicing one of the alternative therapies expressly authorized by A.B. 286 and defined in R213-97, homeopathic physicians may prescribe:

(a) Any controlled substance listed in schedule I, II, III, IV or V as set forth in chapter 453 of NRS, so long as both administration and dosage are medically appropriate according to the standards applicable to that alternative therapy, except that a homeopathic physician may not prescribe "narcotic drugs and opiates that are listed as schedule II controlled substances pursuant to chapter 453 of NRS, except as those substances may be described for use in the official Homeopathic Pharmacopoeia of the United States." (R213-97.)

(b) Any dangerous drug that is defined in chapter 454 of NRS so long as both administration and dosage are medically appropriate according to the standards applicable to that alternative therapy.

(c) Any other allopathic drug available by prescription so long as both administration and dosage are medically appropriate according to the standards applicable to that alternative therapy.

Finally, it is the opinion of this office that, in general, the definitions contained in the regulation of the Homeopathic Board, R213-97, do not exceed the Board's statutory authority and are consistent with legislative intent. However, with respect to the definition of one alternative therapy, orthomolecular medicine, particularly that branch of it that concerns chelation or other forms of detoxification by means of intravenous infusion, there is a significant question whether the regulation is consistent with legislative intent. Nevertheless, in light of the presumption of validity that accompanies every regulation and taking into consideration that the Legislative Commission did not object to the regulation and that the Legislature took no corrective action during the 1999 session, we are inclined to believe that a court of competent jurisdiction would be more likely than not to find the portion of the regulation consistent with legislative intent. In any event. we conclude that such a court would not invalidate the regulation in its entirety.

If you have any further questions regarding this matter, please do not hesitate to contact this office.

Very truly yours,

Brenda J. Erdoes
Legislative Counsel

By_____
William B. R. Daines
Deputy Legislative Counsel

By_____
Jan K. Needham
Principal Deputy Legislative Counsel

WBDR:dtm
Ref No. 9907061127

The Division has implicit authority to collect delinquent supervision fees and restitution regardless of whether the offender is discharged from supervision. Unless already deemed a judgment by statute, the delinquency must be reduced to a judgment. Then, collection procedures under NRS 176.064 should be followed. If the Division uses a collection agency, that agency would have to be paid pursuant to subsection 1 of NRS 176.064. Any collection agency contract would have to conform with the MODEL CONTRACT FORM BOOK published by the Attorney General.

FRANKIE SUE DEL PAPA
Attorney General

By: JOE WARD, JR.
Deputy Attorney General

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AGO 99-06 HOMEOPATHIC MEDICINE; PHARMACY BOARD; CONTROLLED SUBSTANCES: The Homeopathic Medicine Board's regulation allowing for the prescription of pharmaceutical preparations is invalid. The regulation exceeds the grant of statutory authority delegated to the Homeopathic Medicine Board in light of the Legislature's 1997 action on A.B. 286 deleting pharmaceutical medicine from the definition of homeopathy.

Carson City, February 11, 1999

Mr. Keith W. Macdonald, Executive Secretary, Nevada State Board of Pharmacy, 1201 Terminal Way, #212, Reno, Nevada 89502-3257

Dear Mr. Macdonald:

You have posed the following question.

## QUESTION

May a singly licensed homeopathic physician prescribe controlled substances as defined in NRS chapter 453 or dangerous drugs as defined in NRS chapter 454 as "pharmaceutical preparations" within the nontraditional therapies described in revised Homeopathic Board regulation LCB File No. R213-97?

## ANALYSIS

In the 1997 Legislative Session, the Homeopathic Board (Board) proposed a bill expanding the definition of homeopathic medicine and homeopathy. A portion of the first draft of A.B. 286 set forth:

> "Homeopathic medicine" or "homeopathy" means a system of medicine employing substances of animal, vegetable, chemical or mineral origin, including, *without limitation:*
> 2. Noninvasive electrodiagnosis, cell therapy, neural therapy, herbal therapy, neuromuscular integration, orthomolecular therapy, nutrition, *intravenous infusion, chelation therapy and pharmaceutical medicine.* (Emphasis added.)

While testifying in legislative committee in support of this proposed language, Board member, Dr. Fuller Royal, stated his belief that the Board was competent to decide whether licensees or applicants who came before the Board were qualified to write prescriptions for anti-

inflammatory or antibiotic medications. Dr. Royal stated the practice of homeopathic medicine did not call for the use of the above mentioned medications. Nevertheless, if a physician was singularly licensed under the Board, a patient needing a prescription would have to go to another physician in order to obtain the prescription. Dr. Royal thought this procedure was unnecessary. *See Hearing on A.B. 286 Before the Assembly Committee on Commerce*, 1997 Legislative Session, (March 31, 1997).

After the Assembly Committee on Commerce heard strong objections from the Nevada Medical Association and other allopathic physicians on the subject of singly licensed homeopathic physicians prescribing controlled substances and dangerous drugs, the Legislature *deleted* all of the language highlighted above in the first draft of A.B. 286. After the amended version of A.B. 286 was enacted in 1997, the definition of "homeopathic medicine" and "homeopathy" set forth in NRS 630A.040 read as follows:

> "Homeopathic medicine" or "homeopathy" means a system of medicine employing substances of animal, vegetable, chemical or mineral origin, including:
> 1. Nosodes and sarcodes, which are:
> (a) Given in micro-dosage, except that sarcodes may be given in macro-dosage;
> (b) Prepared according to homeopathic pharmacology by which the formulation of homeopathic preparations is accomplished by the methods of Hahnemannian dilution and succussion or magnetically energized geometric patterns applicable in potencies above 30X, as defined in the official Homeopathic Pharmacopoeia of the United States; and
> (c) Prescribed by homeopathic physicians or advanced practitioners of homeopathy according to the medicines and dosages in the Homeopathic Pharmacopoeia of the United States,
> in accordance with the principle that a substance which produces symptoms in a healthy person can eliminate those symptoms in an ill person.
> 2. Noninvasive electrodiagnosis, cell therapy, neural therapy, herbal therapy, neuromuscular integration, orthomolecular therapy and nutrition.

The amended version of NRS 630A.040 did not include the terms *intravenous infusion, chelation therapy, and pharmaceutical medicine* within the definition of "homeopathic medicine" and "homeopathy."

In December 1997, the Board adopted regulations within the Nevada Administrative Code (NAC) describing the nontraditional therapies set forth within NRS 630A.040(2). The descriptions of neural therapy and orthomolecular therapy both included the ability for homeopathic physicians to use pharmaceutical medicines. The descriptions of these nontraditional therapies set forth in part:

> Neural therapy. 1. Neural therapy is the use of any or all local anesthetics, vitamins, minerals, homeopathic medications, herbal extracts or any other medicinal or pharmaceutical substance for intravenous injection, for injection into acupuncture, acupressure, or trigger points, or into nerve ganglia. . . .
> . . . .
> Orthomolecular therapy. Orthomolecular therapy is the treatment and prevention of disease by the expert adjustment of the body's natural chemical constituents on the molecular level, and includes:
> 1. The prescription of topical and oral supplements, pharmaceutical medicines, the intravenous infusion of various substances, including vitamins, amino acids, peptides, polypeptides, pharmaceutical medications, homeopathic medications, ozone and other bio-oxidative substances, chelating agents such as . . . (EDTA), . . . (DMSO), . . . .

This regulation, LCB File No. R213-97 was considered by the Legislative Commission on June 26, 1998. After hearing from various medical professionals, the Legislative Commission voted to object to the regulation as exceeding the grant of statutory authority delegated to the Board. Commission members expressed concerns that allowing a singly licensed homeopathic physician to prescribe and dispense pharmaceutical medicine would improperly expand the jurisdiction of the Board beyond the 1997 Legislature's definition of homeopathic medicine. *See* Minutes of the Legislative Commission (June 26, 1998).

The Board thereafter revised the regulations and adopted them in their present form. Revised LCB File No. R213-97 contained language allowing homeopathic physicians to use "pharmaceutical preparations," instead of "pharmaceutical medicines," in conjunction with neural therapy and orthomolecular therapy. The revised regulation set forth in part:

> (b) "Neural therapy" to mean the injection of vitamins, minerals, homeopathic medications, herbal extracts or other medicinal or pharmaceutical preparations into the:
> (1) Acupuncture, acupressure or trigger points; or
> (2) Ganglia,
> of a patient to control pain or produce other beneficial effects.
> . . . .
> (d) "Orthomolecular therapy" to mean the treatment and prevention of disease, including, without limitation, infection, malignancy and degenerative illness, by adjusting the natural chemical constituents of the body on the molecular level. the term includes, without limitation:
> (1) The prescription of topical and oral supplements and pharmaceutical preparations; and
> (2) The intravenous infusion of vitamins, amino acids, peptides, polypeptides, pharmaceutical preparations, homeopathic medications, ozone, bio-oxidative substances or chelating agents, . . . .
> 2. . . . .
> (c) "Pharmaceutical Preparations" does not include narcotic drugs or opiates that are listed as schedule II controlled substances pursuant to chapter 453 of NRS, except as those substances may be described for use in the official Homeopathic Pharmacopoeia of the United States.

The Legislative Commission reviewed the revised Board regulation on December 18, 1998. Much of the discussion in this Legislative Commission hearing centered on the phrase "pharmaceutical preparations" and what was meant by the use of that phrase within the regulation. From this discussion, it appeared that there was an intent within the revised regulation to allow a singly licensed homeopathic physician to, at least in some limited fashion, prescribe some controlled substances as listed in NRS chapter 453 and dangerous drugs as listed in NRS chapter 454. The Legislative Commission neither approved nor objected to the revised regulation due to the divided nature of the votes within the Commission.

You have requested the present legal opinion because the term "pharmaceutical preparations" is not typical of the terms used within NRS chapters 453 and 454. Board members clarified in the Legislative Commission hearing an intent to interpret the phrase "pharmaceutical preparations" as permitting a singly licensed homeopathic physician to prescribe some controlled substances and dangerous drugs as listed within NRS chapters 453 and 454. We believe this interpretation renders the regulation invalid because the Legislature specifically denied the power for singly licensed homeopathic physicians to prescribe such controlled substances and dangerous drugs through the 1997 legislation on A.B. 286. The regulation cannot restore a power that the Legislature specifically took out of a piece of legislation.

A regulation is invalid if it exceeds the statutory authority delegated by the Legislature to an administrative agency. NRS 233B.110. When the Legislature specifically deleted the term "pharmaceutical medicine" from the definition of homeopathy, its clear intent in enacting the remainder of A.B. 286 was to prohibit the singly licensed homeopathic physician from having the ability to prescribe controlled substances and dangerous drugs in the same manner as an allopathic physician. The Board could not, under the guise of interpreting nontraditional therapies, extend the prescription power back into NRS chapter 630A and thereby give the statutes expanded effect beyond the grant of the Legislature's delegated authority. *Boulware v. State, Dept. Human Resources*, 103 Nev. 218, 737 P.2d 502 (1987); *Hager v. Nevada Medical Legal Screening Panel*, 105 Nev. 1, 767 P.2d 1346 (1989).

## CONCLUSION

If singly licensed homeopathic physicians find the need to prescribe controlled substances or dangerous drugs as listed within NRS chapters 453 and 454, they should obtain a clear grant of such power through statutory amendments made by the Legislature. To date, the Legislature has specifically denied such power to singly licensed homeopathic physicians. Revised NAC regulation LCB File No. R213-97 exceeds the scope of delegated statutory authority and is therefore invalid. We believe that our conclusion in Op. Nev. Att'y Gen. No. 93-21 (September 20, 1993), continues to accurately describe the limited ability of singly licensed homeopathic physicians to possess, dispense, and administer controlled substances and dangerous drugs.

FRANKIE SUE DEL PAPA
Attorney General

By: ROBERT L. AUER
Senior Deputy Attorney General

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AGO 99-07 DRIVING UNDER THE INFLUENCE; JUVENILES: A prior DUI, adjudicated by a juvenile court, is not a conviction under Nevada Statutes. Prior offenses for the purposes of enhancement of the penalty for a DUI must be evidenced by a conviction.

Carson City, February 24, 1999

Marla Zlotek, Deputy District Attorney, Nye County District Attorney's Office, Post Office Box 593, Tonopah, Nevada 89049

Dear Ms. Zlotek:

You have asked the Attorney General for an opinion regarding the following question:

## QUESTION ONE

If a juvenile is adjudicated delinquent for the offense of driving under the influence (DUI), is that adjudication considered a prior conviction for purposes of subsequent DUI prosecution and sentencing enhancement?

## ANALYSIS

The following example is given to illustrate the question:

Pursuant to Title 21, Code of Federal Regulations, Section 1300.01(b28), the term mid-level practitioner means an individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice. Examples of mid-level practitioners include, but are not limited to, health care providers such as nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists and physician assistants who are authorized to dispense controlled substances by the state in which they practice.

| | |
|---|---|
| **AMB** | Ambulance Service |
| **AS** | Animal Shelters |
| **CC** | Certified Chiropractor |
| **DOM** | Doctors of Oriental Medicine |
| **ET** | Euthanasia Technicians |
| **HMD** | Homeopathic Physician |
| **MP** | Medical Psychologists |
| **ND** | Naturopathic Physician |
| **NH** | Nursing Homes |
| **NP** | Nurse Practitioners |
| **OD** | Optometrists |
| **PA** | Physician Assistants |
| **RPH** | Registered Pharmacists |

**Table Description**

The table represents the controlled substances authority for Mid-level Practitioner's by discipline within the state of which they practice. It indicates the categories of Mid-Level Practitioners by State and the licensing authority granted to each category within that particular State through the Drug Enforcement Administration (DEA). If authority is granted, specific schedules are listed along with any special instructions like administer only, dispense only or order only. It may also indicate if the DEA is reviewing a new law to see if it is in fact consistent with the issuance of a DEA registration for controlled substances. If authority is **NOT** granted for a particular category, a "**NO**" will be indicated. The Drugs and drug products that come under the Controlled Substances Act are divided into five schedules. Some examples in each schedule are outlined below.

**Schedule I substances (1)**

The substances in this schedule are those that have no accepted medical use in the United States and have a high abuse potential. Some examples are heroin, marihuana, LSD, MDMA, peyote.

**Schedule II/IIN substances (2/2N)**

The substances in this schedule have a high abuse potential with severe psychic or physical dependence liability. Schedule II controlled substances consist of certain narcotic, stimulant and depressant drugs. Examples of Schedule II narcotic controlled substances are: opium, morphine, codeine, hydromorphone (Dilaudid), methadone, pantopon, meperidine (Demerol), and hydrocodone (Vicodin®). Examples of Schedule IIN non-narcotic would be Amphetamine, Methamphetamine, Nabilone.

**Schedule III/IIIN substances (3/3N)**

The substances listed in this schedule have an abuse potential less than those in Schedules I and II, and include compounds containing limited quantities of certain narcotic drugs (Schedule 3) and non-narcotic drugs (Schedule 3N) such as: codeine (Tylenol with Codeine), derivatives of babituric acid except those listed in another schedule, nalorphine, benzphetamine, chlorphentermine, clortemine, phendimetrazine, paregoric and any compound, mixture, preparation or suppository dosage form containing amobarbital, secobarbital or pentobarbital. Examples of Schedule III narcotics include: products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with Codeine®), and buprenorphine (Suboxone®). Examples of Schedule IIIN non-narcotics include: benzphetamine (Didrex®), phendimetrazine, ketamine, and anabolic steroids such as Depo®-Testosterone.

**Schedule IV substances (4)**

The substances in this schedule have an abuse potential less than those listed in Schedule III and include such drugs as: barbital, phenobarbital, chloral hydtrate, clorazepate (Tranxene), alprazolam (Xanax), Quazepam (Dormalin).

**Schedule V substances (5)**

The substances in this schedule have an abuse potential less than those listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotic and stimulant drugs generally for antitussive, antidiarrheal and analgesic purposes. Some examples are buprenorphine and propylhexedrine.

**Table Key**

| | |
|---|---|
| **2, 2N, 3, 3N, 4, 5** | Schedule categories |
| **Rx's** | Prescriptions |
| **CRNA** | Certified Registered Nurse Anesthetists |
| **CNM** | Certified Nurse Midwives |
| **Per formulary** | Per the directives written out by the state licensing board. |

*MID LEVEL PRACTITIONERS - Controlled Substance Authority by Discipline within State*

**Last Updated: 12/2/2022**

| STATE | AMB | AS | CC | DOM | ET | HMD | MP | ND | NH | NP | OD | PA | RPH |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Ambulance Service | Animal Shelters | Certified Chiropractor | Doctors of Oriental Medicine | Euthanasia Technicians | Homeopathic Physician | Medical Psychologist | Naturopathic Physician | Nursing Homes | Nurse Practitioners | Optometrists | Physician Assistants | Registered Pharmacists |
| **Alabama** | NO | 2N & 3N Sodium Pentobarbital & Sodium Pentobarbital W/Lidocaine Line 1 Animal Shelter Line 2 ET's Name administer / procure | NO | NO | NO | NO | NO | NO | NO | 2,2N,3, 3N, 4, 5 Administer & Prescribe Only. Special permit for 2/2N | 3, 3N, 4, 5 Administer & Prescribe | 2,2N,3, 3N, 4, 5 Prescribe, Dispense & Administer. Special permit for 2/2N | NO |
| **Alaska** | NO | 2N & 3N Sodium Pentobarbital & Sodium Pentobarbital W/Lidocaine Line 1 Animal Shelter Line 2 ET'S Name administer / procure | NO | NO | 2N & 3N Administer Only | NO | NO | NO | NO | 2, 2N, 3, 3N, 4, 5 Prescribe, Dispense, Administer, procure | 3, 4, 5 Prescribe Prescribe 2 Only for Hydrocodone Products | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense, Procure | NO |
| **Arizona** | NO | 2N & 3N Only Law Enforcement or City Animal Shelter administer / procure | NO | NO | NO | 2, 2N, 3, 3N, 4, 5 Prescribe, Dispense, Administer | NO | 2, 3, 3N, 4, 5 Prescribe, Dispense, Administer, procure | NO | 2, 2N, 3, 3N, 4, 5 Prescribe, Order, Administer, procure | 3, 3N Prescribe, Dispense, Administer Prescribe 2 Only for Hydrocodone Products | 2, 2N, 3, 3N, 4, 5 Procurement limited to samples only | NO |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Arkansas** | NO | 2N & 3N Line 1 Animal Shelter Line 2 ET'S Name administer / procure | NO | NO | NO | NO | NO | NO | NO | 3,3N,4,5 APRNs Administer, Order, Prescribe 2 for Hydrocodone Products Only with a Collaborative Practice Agreement. May be extended to C2 and C2N drugs if in accordance with Arkansas Act 593 | 3, 3N, 4, 5 Prescribe 2 Only for Hydrocodone Products | 2, 2N, 3, 3N, 4, 5 Prescribe, Dispense, Administer, Procure | NO |
| **California** | NO | NO | NO | NO | 2N FOR Sodium Pentobarbital ONLY Line 1 RVT Line 2 Shelter administer / procure | NO | NO | 3, 3N, 4 & 5 Prescribe Only | NO | 2, 2N, 3, 3N, 4, 5 Prescribe, Dispense, Administer NOTE: 2 Requires Continuing Education | 2, 3, & 4 Prescribe Only for Hydrocodone, Codeine, & Tramadol Only (3 day Rx only) | 2, 2N, 3, 3N, 4, 5 Prescribe, Dispense, Administer | 2, 2N, 3, 3N, 4, 5 Prescribe Only |
| **Colorado** | 2, 2N, 3, 3N, 4, 5 Line 1 AMB Line 2 DR's Name/ Administer, Dispense and Procure | 2N & 3N Only Law Enforcement or City Animal Shelter administer / procure | NO | NO | NO | NO | NO | NO | NO | Prescribe 2, 2N, 3, 3N, 4, 5 May Dispense & Administer Samples CRNA's/APN's may procure | Prescribe Only 3, 3N, 4, 5 Prescribe 2 Only for Hydrocodone Products | Prescribe & Dispense 2, 2N, 3, 3N, 4, 5 | NO |
| **Connecticut** | NO | NO | NO | NO | NO | NO | NO | NO | NO | 2, 2N, 3, 3N, 4, 5 Prescribe, Dispense, Administer, procure | 2, 2N, 3, 3N, 4, 5 Prescribe, Dispense, Administer | 2, 2N, 3, 3N, 4, 5 Prescribe, Dispense, Administer, procure | NO |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Delaware** | NO | NO | NO | NO | NO | NO | NO | NO | NO | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense, procure | 3, 4, 5 Prescribe Prescribe 2 Only for Hydrocodone Products 72 hour supply | Prescribe 2, 2N, 3, 3N, 4, 5 May Administer & Dispense Samples | NO |
| **District of Columbia** | 2, 2N, 3, 3N, 4, 5 Administer, Dispense and Procure | NO | NO | NO | NO | NO | NO | 3N for Testosterone Only Prescribe, Administer & Dispense, | NO | 2, 2N, 3, 3N, 4, 5 Prescribe Only | NO | 2, 2N, 3, 3N, 4, 5 Prescribe, Dispense & Procure | NO |
| **Florida** | NO | 2N, 3N, Sodium Pentobarbital & Sodium Pentobarbital w/Lidocaine administer / procure | NO | NO | NO | NO | NO | NO | NO | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense only in accordance with state law | 3, 4 Administer, Prescribe only (APAP W/Codeine & Tramadol) Requires 20 hrs. CME | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense only in accordance with state law | NO |
| **Georgia** | NO | NO | NO | NO | NO | NO | NO | NO | NO | 3, 3N, 4, 5 Prescribe, Administer & Dispense | 3, 3N, 4 Prescribe 2 Only for Hydrocodone Products | 3, 3N, 4 & 5 Prescribe Only | NO |
| **Guam (TT)** | NO | 2N & 3N administer / procure | NO | NO | 2N & 3N administer | NO | NO | NO | NO | APRN's can Prescribe 2, 2N, 3, 3N, 4, 5 | NO | 4 & 5 Only Prescribe, Dispense & Administer | NO |
| **Hawaii** | 2, 2N, 3, 3N, 4, 5 LINE 2 DR'S NAME Administer, Dispense and Procure | NO | NO | NO | NO | NO | NO | NO | 2, 2N, 3, 3N, 4, 5 | 2.2n,3,3N,4,5 Administer & Prescribe | NO | 3, 3N, 4 & 5 Prescribe, Dispense, Administer May Write Orders for Inpatients for 2-5 | NO |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Idaho** | 2, 2N, 3, 3N, 4, 5 Administer, Dispense and Procure | 2N, 3, 3N, 4 Administer & Procure Only | NO | NO | NO | NO | 2N, 3N, 4, 5 Prescribe Only | NO | NO | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense, procure | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense | 2, 2N, 3, 3N, 4, 5 Prescribe per Board authorization and per prescriptive practice of supervising physician. Can administer and dispense per Delegation of Service agreement. | 2, 2N, 3, 3N, 4, 5 Administer, Prescribe & Dispense (pursuant to collaborative agreement with prescriber) |
| **Illinois** | NO | 2N & 3N Line 1 Animal Shelter Line 2 ET'S Name administer / procure | NO | NO | NO | NO | 3N, 4, 5 Prescribe Only per 225 ILCS 15/14.3 (d) | NO | NO | 2N, 3, 3N, 4, 5 Prescribe, Dispense & Administer Only Prescribe 30 day supply for schedule 2 | 3, 4, 5 Prescribe Prescribe 2 Only for Hydrocodone Products | 2N, 3, 3N, 4, 5 Prescribe, Dispense & Administer Only Prescribe 30 day supply for schedule 2 | NO |
| **Indiana** | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Procure | 2N & 3N Sodium Pentobarbital, Telazol, Ketamine administer / procure | NO | NO | NO | NO | NO | NO | NO | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense, procure | 4 Prescribe, Administer & Dispense Tramadol Only | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense, procure | NO |
| **Iowa** | NO | 2, 2N, 3, 3N administer / procure | NO | NO | NO | NO | 2N, 3N, 4, 5 Prescribe Only | NO | 2, 2N, 3, 3N, 4, 5 | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense, procure | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense | 2, 2N, 3, 3N, 4, 5 NO 2 Depressants Prescribe, administer, dispense, procure | NO |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Kansas** | 2, 2N, 3, 3N, 4, 5 Administer, Dispense and Procure | NO | NO | NO | NO | NO | NO | NO | NO | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense, Procure (pursuant to collaborative agreement with prescriber) | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense, procure | NO |
| **Kentucky** | NO | 2N & 3N Line 1 Animal Shelter Line 2 ET'S Name administer / procure | NO | NO | NO | NO | NO | NO | NO | 2, 2N, 3, 3N, 4, 5 Prescribe Only | 3, 3N, 4, 5 Prescribe 2 Only for Hydrocodone Products | NO | NO |
| **Louisiana** | NO | 2, 2N, 3, 3N Administer, Dispense & Procure Line 1 Animal Shelter Line 2 ET'S Name | NO | NO | NO | NO | 2, 2N, 3, 3N, 4 & 5 Prescribe Only | NO | NO | 3, 3N, 4, 5 2, 2N Prescribe & Dispense for Attention Deficit Disorder Only | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer | 2, 2N, 3, 3N, 4, 5 Prescribe, Order, & Administer to the extent delegated by the supervising physician | NO |
| **Maine** | NO | 2N3N administer / procure | NO | NO | NO | NO | NO | NO | NO | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense, procure | 3, 3N, 4, 5 Prescribe, Administer & Dispense | 2, 2N, 3, 3N, 4, 5 Prescribe & Dispense | NO |
| **Maryland** | NO | 2N & 3N Procure & Administer Sodium Pentobarbital | NO | NO | NO | NO | NO | NO | 2,2N,3,3N,4,5 adminster only | 2, 2N, 3, 3N, 4 & 5 Prescribe, Administer & Dispense, procure | NO | 2, 2N, 3, 3N, 4, 5 Prescribe & Administer | NO |
| **Massachusetts** | NO | NO | NO | NO | NO | NO | NO | NO | NO | 2, 2N, 3, 3N, 4, 5 Administer, Prescribe & Procure Only | 3N, 4, 5 Administer, Prescribe, Dispense, Procure | 2, 2N, 3, 3N, 4, 5 Administer, Prescribe & Procure Only | 2,2N,3,3N,4, 5 Prescribe only Institutional pharmacist only, No Retail |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Michigan** | NO | 2N & 3N Administer, Dispense & Procure for Sodium Pentobarbital | NO | NO | NO | NO | NO | NO | NO | 2, 2N, 3, 3N, 4, 5 Prescribe No CDS required 2 requires a letter | 3, 3N, 4, 5 Prescribe 2 Only for Hydrocodone Products | 2, 2N, 3, 3N, 4, 5 Prescribe No CDS required 2 requires a letter | NO |
| **Minnesota** | NO | NO | NO | NO | NO | NO | NO | NO | NO | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense, procure | 4 & 5 | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense, procure | NO |
| **Mississippi** | NO | NO | NO | NO | NO | NO | NO | NO | NO | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense, procure | 2, 2N, 3, 3N, 4 & 5 Prescribe | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense, procure | NO |
| **Missouri** | 2, 2N, 3, 3N, 4, 5 Administer, Dispense and Procure | NO | NO | NO | NO | NO | NO | NO | 2, 2N, 3, 3N, 4, 5 | 3, 3N, 4, 5 APRNs Administer, Dispense & Prescribe 2 & 3 for 5 day supply only 2 Only for Hydrocodone Products CS RX license & BNDD & prof license needed (Collaborative Practice Arrangement) | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense | 3, 3N, 4, 5 Administer, Dispense & Prescribe 2 & 3 for a 5 day supply only for Hydrocodone Products CS RX license & BNDD & prof license needed (Collaborative Practice Arrangement) | NO |
| **Montana** | 2, 2N, 3, 3N, 4, 5 Line 1 AMB Line 2 Medical Director Administer, Dispense and Procure | 2N, 3N administer / procure | NO | NO | 2N, 3N Administer Only | NO | NO | 2, 2N 3, 3N, 4, 5 | NO | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense, procure | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense | 3, 3N, 4, 5 34 day Supply Only for 2 & 2N | 2, 2N, 3, 3N, 4, 5 Administer, Procure, Dispense & Prescribe (Pharmacy Practice Agreement) |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Nebraska** | 2, 2N, 3, 3N, 4, 5 Administer, Dispense and Procure | NO | NO | NO | NO | NO | NO | NO | NO | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer, Dispense & Procure | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense | 2, 2N, 3, 3N, 4, 5 Prescribe Only | NO |
| **Nevada** | NO | 2N 3N administer / procure | NO | NO | 2N Administer ONLY | 2, 2N, 3, 3N, 4, 5 | NO | NO | NO | 2, 2N, 3, 3N, 4, 5 Prescribe, Dispense, Administer, procure | 2, 2N, 3, 3N, 4, 5 Prescribe & Administer Only | 2, 2N, 3, 3N, 4, 5 Prescribe, Dispense, Administer, procure | NO |
| **New Hampshire** | NO | NO | NO | NO | NO | NO | NO | 2N for ADHD stimulants 3, 3N, 4, 5 Prescribe Only | NO | 2, 2N, 3, 3N, 4, 5 From Formulary Prescribe, Dispense, Administer, Procure | 3, 3N, 4 Prescribe, Dispense | 2, 2N, 3, 3N, 4, 5 Prescribe, Dispense, Administer, Procure | NO |
| **New Jersey** | NO | 2N Administer, Dispense & Procure for Sodium Pentobarbital | NO | NO | NO | NO | NO | NO | NO | 2, 2N, 3, 3N, 4, 5 Prescribe | 3, 3N, 4, 5 Prescribe 2 Only for Hydrocodone Products | 2, 2N, 3, 3N, 4, 5 Prescribe | NO |
| **New Mexico** | 2, 2N, 3, 3N, 4, 5 Administer, Dispense and Procure | 2, 2N, 3, 3N, 4, 5 Only Law Enforcement or City Animal Shelter administer / procure | 3N Prescribe | 3N for Testosterone Only | 2N & 3N administer / procure | NO | 2-5 Psychotropic Controlled Substance, Prescribe Only | NO | NO | 2, 2N, 3, 3N, 4, 5 (Testosterone) Prescribe Procure & Dispense ALSO CNM's Prescribe Only 2, 2N, 3, 3N, 4, 5 ALSO CRNA's Prescribe, Administer 2, 2N, 3, 3N, 4, 5 | 3, 3N, 4, 5 Prescribe, Administer & Dispense Schedule 2 Only for Hydrocodone Products | 2, 2N, 3, 3N, 4, 5 Prescribe Procure & Dispense | 2, 2N, 3, 3N, 4, 5 Administer & Prescribe |
| **New York** | NO | 2N, 3N Sodium Pentobarbital administer / procure | NO | NO | NO | NO | NO | NO | NO | 2, 2N, 3, 3N, 4, 5 Also Nurse Midwives Prescribe, Administer & Dispense, procure | NO | 2, 2N, 3, 3N, 4, 5 RX'S Only | NO |

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| **North Carolina** | 2, 2N, 3, 3N, 4, 5 Line 2 DR'S Name Administer, Dispense and Procure | 2, 2N, 3, 3N administer / procure | NO | NO | NO | NO | NO | NO | 2, 2N, 3, 3N, 4, 5 Administer, Dispense and Procure | 2, 2N, 3, 3N, 4, 5 Prescribe, Dispense and Procure 2-3N Limited to 30 Day Supply | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense | 2, 2N, 3, 3N, 4, 5 Prescribe, Dispense, Administer and Procure 2-3N Limited to 30 Day Supply | 2, 2N, 3, 3N, 4, 5 Prescribe Only |
| **North Dakota** | NO | NO | NO | NO | NO | NO | NO | NO | NO | 2, 2N, 3, 3N, 4, 5 APRN'S 2-5 Prescribe, Administer & Dispense, procure | 3 | 2, 2N, 3, 3N, 4, 5 Prescribe | NO |
| **Ohio** | 2, 2N, 3, 3N, 4, 5Administer, Dispense and Procure | 2N, 3, 3N administer / procure | NO | NO | NO | NO | NO | NO | NO | 2, 2N, 3, 3N, 4, 5 Administer, Prescribe & Procure CRNAs can Procure Only in a Hospital Setting | 2, 3, 4 administer/ prescribe for Hydrocodone Products | 2, 2N, 3, 3N, 4 , 5 Administer, Prescribe & Procure | 2, 2N, 3, 3N, 4, 5 Administer, Prescribe and Dispense |
| **Oklahoma** | 2, 2N, 3, 3N, 4, 5 Line 2 DR'S Name Administer, Dispense and Procure | NO | NO | NO | 2N, 3N administer / procure | NO | NO | NO | NO | 3, 3N, 4, 5 EXCEPT CRNA'S Administer Only, 2, 2N, 3, 3N, 4, 5 | 3, 3N, 4, 5 Prescribe 2 Only for Hydrocodone Products | 2, 2N, 3, 3N, 4, 5 Prescribe & Administer Only | NO |
| **Oregon** | NO | 2N, 3N, 4 administer / procure | NO | NO | 2N, 3N, 4 Administer Only | NO | NO | 2, 2N, 3, 3N, & 5 Prescribe,Dispense,administer,procure 4 Only Per Formulary | NO | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense, procure | **2**, 3, 3N, 4 & 5 Analgesics Per Formulary No Ordering. **2-hydrocodone only** | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense, procure | NO |
| **Pennsylvania** | 2, 2N, 3, 3N, 4, 5 Administer & Procure | NO | NO | NO | NO | NO | NO | NO | NO | 2, 2N - 30 Day Supply, 3, 3N, 4, 5 90 Day Supply Prescribe Only | 3, 4 and 5 Use of Drugs In Practice Is Not To Exceed 6 Weeks | 2, 2N, 3, 3N, 4, 5 Special Addendum Prescribe, Administer & Dispense, procure | NO |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Puerto Rico** | NO | 2N, 3N Administer, Procure | NO | NO | NO | NO | NO | NO | NO | NO | NO | NO | NO |
| **Rhode Island** | NO | NO | NO | NO | NO | NO | NO | NO | NO | CNM & NP 2, 2N, 3, 3N, 4, 5, CNS 2, 2N &4 Prescribe, Administer & Dispense, procure | 3, 3N, 4 & 5 Prescribe Prescribe 2 Only for Hydrocodone Products | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense, Procure | NO |
| **South Carolina** | 2 , 3N, 4 Ketamine only for 3N | 2N, 3N, 4 Administer, Procure for Sodium Pentobarbital | NO | NO | NO | NO | NO | NO | NO | 2- 5 Day Supply 2N - 30 Day Supply 3, 3N, 4 & 5 Prescribe Only | 3, 3N, 4 & 5 Prescribe, Administer & Dispense Schedule 2 Only for Hydrocodone Products | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense | NO |
| **South Dakota** | 2, 2N, 3, 3N, 4, 5 Administer, Dispense and Procure | NO | NO | NO | NO | NO | NO | NO | NO | NP & CNM 2, 2N, 3, 3N, 4, 5Prescribe, Administer & Dispense, procure | 2, 2N, 3, 3N, 4, 5 Prescribe only, Schedule 2 limited to 30 day supply | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense, procure | NO |
| **Tennessee** | 2, 2N, 3, 3N, 4, 5 Line 1 AMB Line 2 Medical Director Administer, Dispense and Procure | 2N FOR Sodium Pentobarbital administer / procure | NO | NO | NO | NO | NO | NO | NO | 2, 2N, 3, 3N, 4 , 5 Prescribe, Dispense, Administer, Procure | 2, 2N, 3, 3N, 4 , 5 Prescribe, Administer & Dispense | 2, 2N, 3, 3N, 4, 5 Prescribe , Dispense & Procure | 2, 2N, 3, 3N, 4, 5 Administer, Prescribe & Dispense (pursuant to collaborative agreement with prescriber) |
| **Texas** | 2, 2N, 3, 3N, 4,5 Administer, Dispense and Procure | 2N, 3N For Sodium Pentobarbital administer / procure | NO | NO | NO | NO | NO | NO | NO | 3, 3N, 4, 5 Prescribe & Administer 2, 2N* Prescribing/ Ordering. *Hospital / Hospice Only | 2 Administer Only 3, 3N, 4, 5 Prescribe & Administer | 3, 3N, 4, 5 Prescribe & Administer 2, 2N* Prescribing/ Ordering. *Hospital / Hospice Only | NO |

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|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Utah** | NO | 2N, 3N Only Law Enforcement or City Animal Shelter<br><br>Line 2 DVM Name administer / procure | NO | NO | NO | NO | NO | 3N Administer & Prescribe Only | NO | 2, 2N, 3, 3N, 4, 5 Per Formulary Prescribe, Administer & Dispense, procure | 4 & 5 3 Prescribe & Administer Only No More Than 72 Hours Dose Prescribe 2 Only for Hydrocodone Products | 2, 2N, 3, 3N, 4 , 5 Prescribe & Administer Only | 2, 2N, 3, 3N, 4, 5 Prescribe Only Persuant to Collaborative Practice Agreement with Practitioner |
| **Vermont** | NO | 2,2N/3N administer / procure | NO | NO | NO | NO | NO | Prescribe 2, 2N*, 3, 3N, 4, 5 Testosterone, Codeine, Codeine combination products & Carisoprodol only. *Special Endorsement No Formulary | NO | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense, procure | 3, 4, 5 Prescribe Under review 2 and 2N | 2, 2N, 3, 3N, 4, 5 RX from State Formulary | NO |
| **Virgin Islands** | NO | NO | NO | NO | NO | NO | NO | NO | NO | 4, 5 Prescribe & Dispense Only | NO | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer and Dispense | NO |
| **Virginia** | 2, 2N, 3, 3N, 4,5 Administer, Dispense and Procure | 2N, 3N, 4 administer / procure | | NO | NO | NO | NO | NO | NO | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense, procure | 3, 3N, 4 Analgesics Only Prescribe & Administer 2 Only for Hydrocodone (in combination w/acetaminophen) Products | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense, procure | NO |

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| **Washington** | NO | 2N Sodium Pentobarbital administer / procure | NO | NO | NO | NO | NO | 3, 3N, 4, 5 Prescribe, Administer, Dispense/ procure Testosterone and Codeine Only | NO | 2, 2N, 3, 3N, 4 & 5 Prescribe, Administer & Dispense, procure | 3, 3N, 4 & 5 Prescribe, Administer & Dispense Prescribe 2 Only for Hydrocodone Combination Products | Allopathic RX's 2, 2N, 3, 3N, 4 & 5, Osteopathic RX 2, 2N, 3, 3N, 4 & 5 Prescribe, Administer & Dispense, procure | 2, 2N, 3, 3N, 4 & 5 Prescribe Only |
| **West Virginia** | 2, 2N, 3, 3N, 4,5 Administer, Dispense and Procure | 2N-Sodium Pentobarbital only; 3N-Telazol only; Line 1 Shelter name; Line 2 ET Name; administer / procure | NO | NO | NO | NO | NO | NO | NO | 2, 2N Prescribe Only 3, 3N, 4 & 5 Prescribe, Administer & Dispense | 3, 3N, 4, 5 Prescribe, Administer & Dispense May prescribe hydrocodone and hydrocodone containing drugs | 2, 2N, 3, 3N, 4 & 5 Prescribe Only | NO |
| **Wisconsin** | NO | 2N & 3N administer / procure | NO | NO | NO | NO | NO | NO | NO | 2, 2N, 3, 3N, 4 & 5 Prescribe, Administer & Dispense, procure | 3, 3N, 4 & 5 Prescribe, Administer & Dispense 2 Only for hydrocodone products | 2, 2N, 3, 3N, 4 & 5 Prescribe, Administer & Dispense, procure | NO |
| **Wyoming** | NO | 2N, 3N Only Law Enforcement Line 2 DVM administer / procure | NO | NO | 2, 2N, 3, 3N, 4, & 5 Pentobarbital - Based Drugs administer / procure | NO | NO | NO | NO | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer & Dispense, procure | 3, 3N, 4 & 5 Prescribe, Administer & Dispense Prescribe 2 Only for hydrocodone and hydrocodone products | 2, 2N, 3, 3N, 4, 5 RX's ONLY | NO |
| **CNMI - Commonwealth of the Northern Mariana Islands** | NO | NO | NO | NO | NO | NO | NO | NO | NO | 2, 2N, 3, 3N, 4, 5 Prescribe, Administer, Dispense & Procure | NO | 3, 3N, 4, 5 Special Request for 2, 2N | NO |

**21 CFR § 1300.01** - *Individual practitioner* means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

**21 U.S.C. § 802 (21)** The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

# 18

# 18A

Documentation for this Agenda Item will be provided at a later date.

# 18B

Documentation for this Agenda Item will be provided at a later date.

# 18C

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. _____

EXPLANATION – Matter in *italics* is new; matter in brackets [~~omitted material~~] is material to be omitted.

AUTHORITY: §1, NRS 639.070. A REGULATION relating to pharmacy; establishing a process by which the Executive Secretary of the State Board of Pharmacy (Board) may assess an administrative fine against the holder of a license or certificate issued by the Board; describing the offenses for which such a fine may be assessed pursuant to NRS 639.2895, in lieu of initiating disciplinary proceedings pursuant to NRS 639.255; and providing other matters properly relating thereto.

**Section 1.** Chapter 639 of NAC is hereby amended by adding thereto a new section to read as follows:

1. In lieu of initiating disciplinary action pursuant to NRS 639.241 to NRS 639.255, inclusive, for an alleged violation of law by the holder of a certificate, certification, license, or permit issued by the Board, the Executive Secretary may assess an administrative fine against that person pursuant to NRS 639.2895(3) if the person:

(a) Fails to renew or reinstate the certificate, certification, license, or permit after it expires or becomes ineffective due to nonpayment of the applicable fee, and the person thereafter engages in activity for which licensure, registration, authorization, or permission by the Board is required; or,

(b) Violates a regulation of the Board during any period when the person's certificate, certification, license, or permit remains effective.

2. Any fine imposed pursuant to this section shall not exceed $1,000.

3. Any fine imposed pursuant to this section may be appealed to the Board in the manner described in NRS 639.2895(2).

4. For purposes of this section, a person is deemed to be the holder of a certificate, certification, license, or permit issued by the Board for a period of one year after it expires or becomes ineffective due to nonpayment of the applicable fee.

# 18D

Documentation for this Agenda Item will be provided at a later date.

# 19

# 19A

# PROPOSED REGULATION OF THE

# STATE BOARD OF PHARMACY

## LCB File No. R196-22

June 30, 2023

EXPLANATION – Matter in *italics* is new; matter in brackets [~~omitted material~~] is material to be omitted.

AUTHORITY: §§ 1, 2 and 4, NRS 453.221, 639.070 and 639.2177; § 3, NRS 639.070 and 639.170.

A REGULATION relating to pharmacy; requiring a facility for treatment with narcotics to obtain a license to administer opioid agonist treatment medication; requiring a dispensing practitioner at such a facility to obtain informed consent before reporting certain information; prescribing certain fees; and providing other matters properly relating thereto.

**Legislative Counsel's Digest:**

Existing law authorizes the State Board of Pharmacy to adopt regulations relating to the registration and control of the dispensing of controlled substances in Nevada. (NRS 453.221) Existing law further authorizes the Board to adopt regulations that: (1) are necessary for the protection of the public relating to the practice of pharmacy; (2) authorize the Executive Secretary of the Board to issue certificates, licenses and permits required for the practice of pharmacy or for the dispensing of controlled substances; and (3) govern the dispensing of poisons, drugs, chemicals and medicines. (NRS 639.070) Existing regulations require a facility for treatment with narcotics, which is a facility certified by the federal government to treat addiction to narcotics using other narcotics, to be licensed by the Division of Public and Behavioral Health of the Department of Health and Human Services. (NAC 449.15445) **Section 1** of this regulation additionally requires a facility for treatment with narcotics to obtain a license from the Board to administer opioid agonist treatment medication and sets forth the requirements to obtain such a license. **Section 1** also requires dispensing practitioners at a facility for treatment with narcotics to obtain informed consent for the reporting of information to a program that tracks prescriptions of certain controlled substances. **Section 2** of this regulation defines certain terms.

Existing regulations prescribe fees for the issuance and biennial renewal of authorization of a facility for treatment with narcotics to prescribe or possess controlled substances. (NAC 639.220) **Section 3** of this regulation clarifies that such fees apply to the investigation or issuance and biennial renewal of a license to administer opioid agonist treatment medication. **Section 4** of this regulation authorizes a facility for treatment with narcotics that is operating on the effective date of this regulation to continue to do so without obtaining such a license until 6 months after that date.

**Section 1.** Chapter 639 of NAC is hereby amended by adding thereto to a new section to read as follows:

*1. A person or public or private facility shall not operate or provide the services of a facility for treatment with narcotics unless the person or facility holds a license to administer opioid agonist treatment medication issued by the Board pursuant to this section.*

*2. A person or public or private facility may apply to the Board for a license to administer opioid agonist treatment medication by submitting an application to the Board on a form prescribed by the Board. The Board shall issue such a license if the applicant meets the requirements sets forth in subsection 3 and pays the fee required by NAC 639.220.*

*3. An applicant for a license pursuant to subsection 2 must:*

*(a) Be certified by the Substance Abuse and Mental Health Services Administration of the United States Department of Health and Human Services pursuant to 42 C.F.R. § 8.11;*

*(b) Hold a license issued by the Division of Public and Behavioral Health of the Department of Health and Human Services pursuant to NAC 449.154 to 449.15485, inclusive, to operate a facility for treatment with narcotics;*

*(c) Be certified by the Division of Public and Behavioral Health of the Department of Health and Human Services pursuant to NRS 458.025; and*

*(d) Ensure that each practitioner who dispenses opioid agonist treatment medication at the facility is registered with the Board pursuant to NRS 453.231 and the Drug Enforcement Administration of the United States Department of Justice to dispense controlled substances.*

*4. Any license issued pursuant to this section is a revocable privilege and a holder of such a license does not acquire any vested right in such a license.*

*5. Each dispensing practitioner practicing at a facility for treatment with narcotics shall, to the extent required by 42 C.F.R. § 2.36, obtain informed consent for the reporting of information to the computerized program to track prescriptions for controlled substances established pursuant to NRS 453.162.*

**Sec. 2.** NAC 639.010 is hereby amended to read as follows:

639.010 As used in this chapter, unless the context otherwise requires:

1. "Automated drug dispensing system" means a system that performs operations, other than compounding or administration, related to the storage and dispensing of drugs.

2. "Board" means the State Board of Pharmacy.

3. "Controlled substances" has the meaning ascribed to it in NRS 0.031.

4. "Dangerous drug" has the meaning ascribed to it in NRS 454.201.

5. "Direct supervision" means the direction given by a supervising pharmacist or dispensing practitioner who is:

(a) On the premises of the pharmacy or telepharmacy at all times when the person he or she is supervising is working at the pharmacy or telepharmacy or at a remote site or satellite consultation site; and

(b) Aware of the activities of that person related to the preparation and dispensing of medications, including the maintenance of appropriate records.

6. "Dispensing practitioner" means:

(a) A practitioner to whom the Board has issued a certificate of registration pursuant to NAC 639.742 to dispense controlled substances or dangerous drugs, or both, for human consumption; or

(b) A licensed veterinarian to whom the Board has issued a certificate of registration pursuant to NAC 639.7423 to dispense controlled substances or dangerous drugs, or both, not for human consumption.

7. "Dispensing technician" means a person who performs technical services in a pharmacy under the direct supervision of a dispensing practitioner and is registered with the Board pursuant to NAC 639.7425.

8. "Dispensing technician in training" means a person who is registered with the Board pursuant to section 1 of LCB File No. R178-22 in order to obtain the training and experience required to be a dispensing technician pursuant to subparagraph (1) of paragraph (c) of subsection 2 of NAC 639.7425.

9. "Executive Secretary" means the Executive Secretary employed by the Board pursuant to NRS 639.040.

10. ***"Facility for treatment with narcotics" has the meaning ascribed to it in NAC 449.1542.***

***11.*** "Federally-qualified health center" has the meaning ascribed to it in 42 U.S.C. § 1396d(l)(2)(B).

~~[11.]~~ ***12.*** "Federally-qualified health center vehicle" means a vehicle that meets the requirements of paragraph (c) of subsection 1 of section 3 of LCB File No. R004-19.

~~[12.]~~ ***13.*** "Licensed veterinarian" has the meaning ascribed to it in NRS 638.007.

~~[13.]~~ ***14.*** "Oncology group practice" means two or more dispensing practitioners who practice oncology in a group practice.

~~[14.]~~ ***15. "Opioid agonist treatment medication" has the meaning ascribed to it in 42 C.F.R. § 8.2.***

*16.* "Pharmaceutical technician" means a person who performs technical services in a pharmacy under the direct supervision of a pharmacist and is registered with the Board pursuant to NAC 639.240.

~~[15.]~~ *17.* "Pharmaceutical technician in training" means a person who is registered with the Board pursuant to NAC 639.242 in order to obtain the training and experience required to be a pharmaceutical technician pursuant to subparagraph (3) of paragraph (d) of subsection 2 of NAC 639.240, or who is enrolled in a program of training for pharmaceutical technicians that is approved by the Board.

~~[16.]~~ *18.* "Practitioner" has the meaning ascribed to it in NRS 639.0125.

~~[17.]~~ *19.* "Prescription drug" means a drug or medicine as defined in NRS 639.007 which:

(a) May be dispensed only upon a prescription order that is issued by a practitioner; and

(b) Is labeled with the symbol "Rx only" pursuant to federal law or regulation.

~~[18.]~~ *20.* "Public or nonprofit agency" means a health center as defined in 42 U.S.C. § 254b(a) which:

(a) Provides health care primarily to medically underserved persons in a community;

(b) Is receiving a grant issued pursuant to 42 U.S.C. § 254b or, although qualified to receive such a grant directly from the Federal Government, is receiving money from such a grant under a contract with the recipient of that grant; and

(c) Is not a medical facility as defined in NRS 449.0151.

~~[19.]~~ *21.* "Reproductive healthcare center" means a health facility owned and operated by a nonprofit corporation or a public health center, as defined in subsection 8 of NRS 449.260, principally engaged in providing family planning services and reproductive healthcare,

including, without limitation, the testing, diagnosis and treatment of, or providing of medication to prevent, a sexually transmitted infection or other infection of the urogenital system.

~~[20.]~~ *22.* "Surgical center for ambulatory patients" has the meaning ascribed to it in NRS 449.019.

~~[21.]~~ *23.* "User-based access technology" means software or hardware that restricts access to an automated drug dispensing system to authorized users by requiring two-factor authentication. Authentication factors may include, without limitation, knowledge, hardware tokens or biometric information.

**Sec. 3.** NAC 639.220 is hereby amended to read as follows:

639.220 1. The Board hereby adopts the following schedule of fees:

For the examination of an applicant for registration as a pharmacist ..... Actual cost of the examination

For the investigation or registration of an applicant as a registered pharmacist.....$200

For the investigation, examination or registration of an applicant as a registered pharmacist by reciprocity.....200

For the investigation or issuance of an original license to conduct a retail pharmacy .....500

For the biennial renewal of a license to conduct a retail pharmacy .....500

For the investigation or issuance of an original license to conduct an institutional pharmacy .....500

For the biennial renewal of a license to conduct an institutional pharmacy .....500

For the investigation or issuance of an original license to conduct a pharmacy in a correctional institution .....500

For the biennial renewal of a license to conduct a pharmacy in a correctional institution .....500

For the investigation or issuance of an original license to conduct a pharmacy in a recovery center or ambulatory surgical center licensed by the State Board of Health pursuant to NRS 449.0303 .....500

For the biennial renewal of a license to conduct a pharmacy in a recovery center or ambulatory surgical center licensed by the State Board of Health pursuant to NRS 449.0303 .....500

For the issuance of an original or duplicate certificate of registration as a registered pharmacist .....50

For the biennial renewal of registration as a registered pharmacist .....200

For the reinstatement of a lapsed registration (in addition to the fees for renewal for the period of lapse) .....100

For the initial registration of a pharmaceutical technician, pharmaceutical technician in training, dispensing technician or dispensing technician in training .....50

For the biennial renewal of registration of a pharmaceutical technician, pharmaceutical technician in training, dispensing technician or dispensing technician in training .....50

For the investigation or registration of an intern pharmacist .....40

For the biennial renewal of registration as an intern pharmacist .....40

For the investigation or registration of an advanced practice registered nurse or a physician assistant to prescribe drugs that are not controlled substances .....80

For the biennial renewal of registration of an advanced practice registered nurse or a physician assistant to prescribe drugs that are not controlled substances .....80

For authorization of a physician, advanced practice registered nurse, physician assistant, euthanasia technician, ~~[facility for treatment with narcotics,]~~ researcher, instructional user or any other authorized person, except a practitioner who is a medical intern or resident physician, to prescribe or possess controlled substances .....200

For the biennial renewal of authorization of a physician, advanced practice registered nurse, physician assistant, euthanasia technician, ~~[facility for treatment with narcotics,]~~ researcher, instructional user or any other authorized person, except a practitioner who is a medical intern or resident physician, to prescribe or possess controlled substances .....200

For authorization of a practitioner who is a medical intern or resident physician to prescribe or possess controlled substances .....80

For the biennial renewal of authorization of a practitioner who is a medical intern or resident physician to prescribe or possess controlled substances .....80

For the investigation or issuance of an original license to engage in business as an authorized warehouse or medical products provider .....500

For the biennial renewal of a license to engage in business as an authorized warehouse or medical products provider .....500

For the investigation or issuance of an original license to a manufacturer or wholesaler.....1,000

For the biennial renewal of a license for a manufacturer or wholesaler .....1,000

For the reissuance of a license issued to a pharmacy, when no change of ownership is involved, but the license must be reissued because of a change in the information required thereon.....50

For authorization of a practitioner, other than a licensed veterinarian, to dispense controlled substances or dangerous drugs, or both, for human consumption for each location where the practitioner will dispense controlled substances or dangerous drugs, or both, for human consumption.....300

For the biennial renewal of authorization of a practitioner, other than a licensed veterinarian, to dispense controlled substances or dangerous drugs, or both, for human consumption for each location where the practitioner will dispense controlled substances or dangerous drugs, or both, for human consumption.....300

For authorization of a licensed veterinarian to dispense controlled substances or dangerous drugs, or both, not for human consumption.....150

For the biennial renewal of authorization of a licensed veterinarian to dispense controlled substances or dangerous drugs, or both, not for human consumption.....150

For the investigation or issuance of an original license for an automated drug dispensing system.....500

For the biennial renewal of a license for an automated drug dispensing system.....500

For the investigation or issuance of an original license to a pharmacy authorizing the use of a mechanical device to furnish drugs and medications for administration to patients at a medical facility.....250

For the biennial renewal of a license to a pharmacy authorizing the use of a mechanical device to furnish drugs and medications for administration to patients at a medical facility.....250

***For the investigation or issuance of an original license for a facility for treatment with narcotics to administer opioid agonist treatment medication.....80***

***For the biennial renewal of a license for a facility for treatment with narcotics to administer opioid agonist treatment medication.....80***

2. The penalty for failure to pay the renewal fee for any license, permit or certificate within the statutory period, as provided in subsection 6 of NRS 639.170, is 50 percent of the renewal fee for each period of delinquency in addition to the renewal fee for each period of delinquency.

3. Any person who has been registered as a pharmacist in this State for at least 50 years is not required to pay the fee for the biennial renewal of a certificate of registration as a registered pharmacist.

4. The provisions of this section concerning the fee for the biennial renewal of the authorization to dispense controlled substances or dangerous drugs do not apply to an advanced practice registered nurse who is required to pay a fee pursuant to NAC 639.870.

5. A practitioner employed by or serving as an independent contractor of a health center:

(a) Which is a federally-qualified health center that provides health care primarily to medically underserved persons in a community; and

(b) Which is not a medical facility as defined in NRS 449.0151,

➥ is not required to pay a fee to the Board for a change of address or for an additional address at which the practitioner dispenses drugs.

6. A practitioner who is exempt from the payment of a fee pursuant to subsection 5 shall notify the Board in writing of each change of address or additional address, or both.

7. In addition to any other fees paid by an applicant for a certificate, license or permit issued pursuant to chapter 639 of NRS, the Board may require that the applicant pay actual costs of inspection incurred by the Board.

**Sec. 4.** 1. Notwithstanding the provisions of section 1 of this regulation, a person or public or private facility who is operating or providing the services of a facility for treatment with narcotics on the effective date of this regulation may continue to operate or provide the services of such a facility without obtaining a license to administer opioid agonist treatment medication pursuant to section 1 of this regulation until 6 months after the effective date of this regulation.

2. As used in this section:

(a) "Facility for treatment with narcotics" has the meaning ascribed to it in NAC 449.1542.

(b) "Opioid agonist treatment medication" has the meaning ascribed to it in 42 C.F.R. § 8.2.

# 20

# 21

# EXECUTIVE SECRETARY REPORT
# September 6-7, 2023

- **FINANCIAL REPORT**
- **TEMPORARY LICENSES**
- **CHANGE OF ADDRESS BUSINESS LIST**
- **Citations & Fines issued pursuant to NRS 639.2895**
- **STAFF ACTIVITIES**
  - Meetings with Other Health Care Boards
- **REPORT TO BOARD**
  - Legislative Update
- **BOARD RELATED NEWS**
- **ACTIVITIES REPORT**
  - Law CE update
  - Renewal
  - State of Nevada Opioid Summit

**September 2023 Temporary Licenses since the last Board Meeting**

| Name | License Type |
|---|---|
| Lakshay Tikeya | Pharmacist |
| Mervyns Fontillas | Pharmacist |
| Dominic Acosta | Pharmacist |
| Chayse Bryant | Pharmacist |
| Aashna Bhola | Pharmacist |
| Krunal Patel | Pharmacist |
| Eileen Leung | Pharmacist |
| Puja Patel | Pharmacist |
| Amanda Presnell | Pharmacist |

| Business Name | License Type |
|---|---|
| Fusion Orthopedics, LLC | Wholesaler |
| OxyGo HQ Florida LLC | Wholesaler |
| Coloplast Corp. | Wholesaler |
| Coloplast Corp. | Wholesaler |

# Citations & Fines issued pursuant to NRS 639.2895

# (Since the last Board Meeting)

- Cease & Desist/Cite & Fine
  - Unlicensed Practice: 14
- Cite & Fine
  - Misfill: 4
  - Unlicensed Practice - 2

Regulation Tracking Log

| Regulation Number and Topic | Workshop Propose To Bd | 30 Days To LCB W/Letter | LCB R0 Number Issued | LCB Return Date | 30 Days Post Public Hearing | Public Hearing Meeting Date | To LCB Final W/ Cov./Info | Secretary of State File Date |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |
| 639.NEW – Criminal Conviction/ Administrative Action Reporting (Licensee) | 10/10/19 | 10/18/19 | R094-19 | 11/29/19 | 01/29/20 | 03/19/20 Postponed per Brett 4/22/21 Brett to review with Dave. | | |
| 639.220 - licensing and regulation of a facility to dispense controlled substances and dangerous drugs if the facility is licensed by the State Board of Health (recovery centers) | 03/19/20 – postponed to 06/03/20 | 6/16/20 | R085-20 | 09/17/20 | 10/22/20 12/03/20 | 01/13/21 | 01/29/21 | 04/14/21 |
| 639.NEW - licensing and regulating the practice of pharmacy (appearance requirements) | 03/19/20 | 3/24/20 | R041-20 | 05/14/20 | 06/09/20 | 07/16/20 | 07/22/20 | 08/26/20 |
| 453.550 – Deschedule Epidiolex | 06/03/20 | 6/16/20 | R090-20 R073-19 | 07/30/20 | 09/11/20 | 10/15/20 | 10/28/20 | 12/29/20 |
| 639.NEW – CS Electronic Transmission Exemption | 06/03/20 | 6/16/20 | R083-20 | 10/15/20 | 10/07/20 | 11/10/20 | 12/12/20 | 12/29/20 |
| 639.464 & 639.468 – P&T Committee vs CPA | 06/03/20 | | | | Dave revising | | | |

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|---|---|---|---|---|---|---|---|---|
| | | | | | (Dave has file) | | | |
| 639.NEW – PT Administer Immunizations | 07/16/20 | 07/21/20 | R142-20 | 08/20/20 | 08/03/20 | 09/03/20 | 09/15/20 | 09/21/20 |
| 453.510 – Schedule I - Designer Benzos | 07/16/20 | 07/21/20 | R143-20 | 12/14/20 | 01/26/21 | 03/03/21 | 03/24/21 | 04/14/21 |
| 453.510 – Schedule II - Kratom | 07/16/20 | 07/21/20 | R144-20 | 12/14/20 Hold per Dave | 03/15/22 | 04/14/22 04/06/22: Removed from agenda. | | |
| NAC 639.742, 639.743, 639.744. and 639.745: Dispensing Practitioners: shared inventory and centralized activities. | 09/03/20 01/13/21 | 03/12/21 | R007-21 | 02/17/22 To Dave for review | 03/11/22 | 04/14/22: Failed 06/02/22:PH | 03/21/22 | 06/13/22 |
| NAC 639.501 – Workplace Assessment Tool | 10/15/20 | 10/21/20 | R165-20 | 11/17/21 | 12/09/21 | 01/13/22 | 01/20/22 | 02/28/22 |
| NAC 639 Pharmacist Practice Location | 10/15/20 | 10/21/20 | R164-20 | 4/28/22 – under review by Dave/ Brett | 11/08/22 | 12/08/22 | *12/28/22 Leg Comm* | 12/29/22 |
| NAC 639 – Cite and Fine for Misfilled Prescriptions | 10/15/20 | 10/21/20 | R166-20 | 08/27/21 | 1/25/22 – Close per Brett/Karly O'Krent | | | |

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|---|---|---|---|---|---|---|---|---|
| NAC 639.220 - Schedule of fees; medical interns and residents reduced fees | 01/13/21 | 02/02/21 | R003-21 | 08/17/21 | 08/26/21 | 10/14/21 | 10/21/21 | 12/22/21 |
| NAC 639.NEW Compounded Drugs (dispensing, supplying, furnishing) | 01/13/21 | 01/20/21 | R002-21 | 09/01/21 | 10/22/21 | 12/02/21 tabled | | |
| NAC 639.715, 639.718, 639.720: Use of mechanical devices to dispense drugs | 03/03/21 06/03/21 | 06/10/21 | R013-21 | 10/28/21 (under review) by Dave/Yenh | 01/19/22 | 03/03/22 | 03/10/22 | 06/13/22 |
| NAC 453: PMP Integration with electronic health records of practitioners | 03/03/21 | 03/12/21 | R008-21 | 07/13/21 | 08/26/21 | 10/14/21 | 10/21/21 | 12/22/21 |
| NAC 639: Reference Standards for Compounding | 06/03/21 | 06/10/21 | R012-21 | | | | | |
| NAV 639: Hormonal Contraceptive Protocol | 07/15/21 | 09/07/21 | R036-21 | 10/27/21 (returned to LCB 11/3/21 for revision) | 12/09/21 | 01/13/22 | 01/14/22 | 02/28/22 |
| NAC 639: Background Check RPH, PT, PTT; increase fees for investigation or issuance or renewal of a license as a manufacturer or wholesaler; application valid for one year; clarify licensing requirements for an outsourcing facility or | 07/15/21 | 07/20/21 | R025-21 | 09/30/21 (under review) by Dave/Yenh | 01/19/22 | 03/03/22 | 03/10/22 | 04/11/22 |

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|---|---|---|---|---|---|---|---|---|
| euthanasia technician. (Senate Bill 408) | | | | | | | | |
| NAC 453.510: Schedule I – Eutylone and fentanyl related substances. | 07/15/21 | 07/20/21 | R023-21 | 09/28/21 | 10/22/21 | 12/02/21 | 12/10/21 | 12/22/21 |
| NAC 453.540: Schedule IV – lemborexant and Remimazolam. | 07/15/21 | 07/20/21 | R024-21 | 08/17/21 | 08/26/21 | 10/14/21 | 10/21/21 | 12/22/21 |
| NAC 639: Allow pharmacists to dispense drugs approved the FDA for human immunodeficiency virus. (Senate Bill 325) | 07/15/21<br>09/02/21 | 09/08/21 | R039-21 | 11/04/21 | 11/05/21<br>Under review by Yenh<br>12/12/21<br>Under review by Dave | 03/03/22 | 03/10/22 | 04/11/22 |
| NAC 639: Prescription information in English and another language (AB 177). | 09/02/21<br>Continued 12/02/21 | 12/08/21 | R119-21 | 2/25/22 to Dave/ Yenh for review | 03/11/22 | 04/14/22<br>07/14/22 | 04/27/22<br>06/10/22-Pulled by Leg Com<br>Scheduled for 07/14/22 Public Hearing<br>To LCB 07/20/22 | 9/27/22<br>Leg Comm – Failed |

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|---|---|---|---|---|---|---|---|---|
| NAC 639.010, 639.240, 639.242, 639.256: PT/PTT registration requirements. | 09/02/21 | 09/08/21 | R041-21 | 4/20/22 – Under review by Dave/Yenh | 04/27/22 | 06/02/22 | 08/17/22 *9/27/22 Leg Comm* | 09/28/22 |
| NAC 639.208: Requirements to obtain a registration as a pharmacist by reciprocity. | 09/02/21 | 09/08/21 | R040-21 | 12/29/21 - Under review by Dave/Yenh | 01/19/22 | 03/03/22 | 03/10/22 | 04/11/22 |
| NAC 639.360: Accreditation of material, course or program (CE) | 12/02/21 | 12/08/21 | R120-21 | 01/10/22 01/26/22: Returned to LCB for changes. 2/20/22 – To Dave/ Yenh for review. 2/18/22 – Returned to LCB for changes. 3/11/22 – returned to LCB for revisions. 4/7/22 – Under review by Dave/Yenh | 04/27/22 | 06/02/22 | 07/05/22 *9/27/22 Leg Comm* | 09/28/22 |

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|---|---|---|---|---|---|---|---|---|
| NAC 453.510: Schedule I – Isotonitazene | 01/13/22 | 01/14/22 | R006-22 | 02/23/22<br>02/24/22 – Under review by Dave/Yenh | 03/11/22 | 04/14/22 | 04/27/22 | 06/13/22 |
| NAC 453B: Prescription Drug Donation Program | 01/13/22 | 01/14/22 | R007-22 | 03/21/22 – Under review by Dave/Yenh | 10/20/22 | 12/01/22 | *12/28/22 Leg Comm* | 12/29/22 |
| NAC 453: Registration of a law enforcement officer engaged in training a canine in drug detection, and add methoxetamine. | 04/14/22 | 04/21/22 | R050-22 | 04/27/22 Under review by Dave/Yenh | 08/05/22 | 09/08/22 | *9/27/22 Leg Comm* | 09/28/22 |
| NAC 639: Requires the holder of any certificate, license or permit issued by the BOP to report certain convictions and administrative actions to the Board. | 04/14/22 | 04/21/22 | R051-22 | 05/05/22 | 06/09/22 | 07/14/22 | 07/20/22<br>*9/27/22 Leg Comm* | 09/28/22 |
| NAC 639: Medical Products Wholesaler | 06/02/22 | 06/09/22 | R085-22 | 07/19/22 | 08/05/22 | 09/08/22 | 09/15/22<br>*9/27/22 Leg Comm* | 09/28/22 |
| NAC 639: Medication Assisted Treatment | 06/02/22 | 06/09/22 | R087-22 | 08/08/22 | 08/31/22 | 10/13/22 | 10/19/22 | 12/29/22 |

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|---|---|---|---|---|---|---|---|---|
| | | | | | | | *12/28/22 Leg Comm* | |
| NAC 639.870: APRN Dispensing License/pharmacy applicant appearance | 06/02/22 | 06/02/22 – Dave revising language. | R086-22 | 06/29/22 07/05/22: under Dave review | | | | |
| NAC 639: Dispensing Technicians | 07/14/22 | 08/03/22 | R178-22 | 9/29/22 Under review by Dave | 10/20/22 | 12/01/22 | *12/28/22 Leg Comm* | 12/29/22 |
| NAC 639: Automated Dispensing Device | 07/14/22 | 08/03/22 | R179-22 | 8/24/22: Under review by Dave | 10/20/22 | 12/01/22 | *12/28/22 Leg Comm* | 12/29/22 |
| NAC 639: Reproductive Health Care Center | 07/14/22 | 08/03/22 | R180-22 | 8/12/22: Under review by Dave LCB returned 9/6/22. 9/13/22: Under review by Dave and Yenh. | 10/20/22 | 12/01/22 | *12/28/22 Leg Comm* | 12/29/22 |

Regulation Tracking Log

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|---|---|---|---|---|---|---|---|---|
| NAC 639: Dispensing Practitioners in Reproductive Healthcare Center: single inventory of dangerous drugs. | 07/14/22 | 07/14/22 – Dave revising language. To LCB 08/03/22 | R181-22 | 8/29/22: Under review by Dave | 08/31/22 | 10/13/22 | 10/19/22 *12/28/22 Leg Comm* | 12/29/22 |
| NAC 453.540: Schedule IV – Daridorexant. | 07/14/22 | 07/19/22 | R170-22 | 08/02/22 | 08/05/22 | 09/08/22 | 09/15/22 *9/27/22 Leg Comm* | 09/28/22 |
| NAC 639: Narcotic Treatment Program | 10/13/22 | 10/19/22 | R196-22 | 06/30/23 07/11/23: to Dave/ Yenh for review | 08/08/23 | 09/07/23 | | |
| NAC 453.310: DEA Registration | 10/13/22 | 10/19/22 | R197-22 | 05/12/23: to Dave/ Yenh 05/26/23: Under review by Yenh/Peter 05/30/23: Hold till final rule on state specific DEA registration requirement. | | | | |

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|---|---|---|---|---|---|---|---|---|
| NAC 639.2973 & NAC 639.2974: Basic Life Support Certification | 10/13/22 | 10/19/22 | R198-22 | 05/12/23 | 06/09/23 | 07/13/23 | 07/21/23<br>08/21/23 Leg Comm | |

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